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**MYTHS AND FACTS ABOUT HUMAN GROWTH**

**HORMONE, B-12, AND OTHER SUBSTANCES**

**Tuesday, February 12, 2008**

**House of Representatives,**

**Committee on Oversight and**

**Government Reform,**

**Washington, D.C.**

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**Committee Hearings**

**of the**

**U.S. HOUSE OF REPRESENTATIVES**



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5 Tuesday, February 12, 2008

6 House of Representatives,

7 Committee on Oversight and

8 Government Reform,

9 Washington, D.C.

10 The committee met, pursuant to call, at 10:00 a.m., in  
11 Room 2154, Rayburn House Office Building, Hon. Henry A.  
12 Waxman [chairman of the committee] presiding.

13 Present: Representatives Waxman, Cummings, Tierney,  
14 Watson, Norton, Sarbanes, Davis of Virginia, Shays, Issa and  
15 Bilbray.

16 Staff Present: Phil Schiliro, Chief of Staff; Phil  
17 Barnett, Staff Director and Chief Counsel; Karen Lightfoot,  
18 Communications Director and Senior Policy Advisor; John  
19 Williams, Deputy Chief Investigative Counsel; Sarah Despres,  
20 Senior Health Counsel; Steve Cha, Professional Staff Member;

21 | Earley Green, Chief Clerk; Teresa Coufal, Deputy Clerk; Caren  
22 | Auchman, Press Assistant; Ella Hoffman, Press Assistant;  
23 | Zhongrui "JR" Deng, Chief Information Officer; Leneal Scott,  
24 | Information Systems Manager; Miriam Edelman, Staff Assistant;  
25 | Bret Schothorst, Special Assistant; David Marin, Minority  
26 | Staff Director; Jennifer Safavian, Minority Chief Counsel for  
27 | Oversight and Investigations; Brian McNicoll, Minority  
28 | Communications Director; Benjamin Chance, Minority Clerk; and  
29 | Jill Schmalz, Minority Professional Staff Member.

30 Chairman WAXMAN. Good morning. The committee will  
31 please come to order.

32 For the last 3 years, our committee has been  
33 investigating the use of performance-enhancing drugs in  
34 professional sports and by high school children. A lot of  
35 developments have surprised me but none more than the fact  
36 that there is a great deal of misinformation and widespread  
37 confusion that surrounds steroids, human growth hormone,  
38 vitamin B-12 and other substances. Even highly paid,  
39 presumably sophisticated professional athletes often seem to  
40 know the myths and not the facts about these substances.

41 That's why we're having today's hearing. It's an  
42 opportunity to provide essential and accurate information not  
43 just to professional athletes, not just to high school kids  
44 but to senior citizens, baby boomers turning 60 and everyone  
45 in between.

46 In previous hearings, experts have testified about the  
47 potentially deadly risks associated with steroid use. The  
48 side effects range from serious damage to the heart and liver  
49 to well-documented psychiatric problems. Steroids can be  
50 especially dangerous for children by impeding normal  
51 development and inflicting long-lasting harm. We will  
52 discuss those issues again today, but we'll also focus  
53 on--our long-overdue attention on the growing use of other  
54 substances.

55           Senator Mitchell's report on the use of  
56 performance-enhancing drugs in baseball found that the use of  
57 human growth hormone by professional baseball players is  
58 rising. Just last week, Sylvester Stallone seemed to be  
59 endorsing the use of HGH to reverse the aging process. It's  
60 an unfortunate reality that what professional athletes and  
61 celebrities do serves as a health guide to millions of  
62 Americans.

63           Even worse, there seems to be an almost unlimited number  
64 of unscrupulous scam artists ready to exploit this reality.  
65 Here's an advertisement that we can see on the screen by  
66 GenF20 that reads, HGH could actually prevent biological  
67 aging. It's like your body is immune to the passage of time.

68           Here are the frequently asked questions from another  
69 product, Growlean 15, that says, our product can be taken at  
70 any age, safely, with no harmful side effects.

71           Well, if any of us search the Internet today, we would  
72 find thousands of similar sites and a blizzard of confusing  
73 claims. It's no wonder that so many are confused by the  
74 facts about HGH. Today, we have a distinguished panel of  
75 experts who are going to tell us, while there are appropriate  
76 uses for HGH, there are also serious risks from abusing this  
77 powerful drug.

78           In adults, HGH is used to treat adult growth hormone  
79 deficiency and the wasting syndrome of late-stage AIDS, both

80 | of which are relatively rare. When HGH is used to treat  
81 | these conditions, there are extensive blood tests used to  
82 | diagnose the patient; and patients being treated with HGH are  
83 | closely monitored by physicians.

84 |         For children, HGH is approved to treat a few uncommon  
85 | conditions such as idiopathic short stature growth hormone  
86 | deficiency and chronic kidney disease. It's also used to  
87 | treat a few genetic diseases such as Turner Syndrome and  
88 | Prader-Willi Syndrome. In these cases, HGH can have a clear  
89 | therapeutic benefit.

90 |         But careful studies conclude that, when it comes to  
91 | reversing the aging process, HGH is more snake oil than cure.

92 |         In 2002, the National Institute on Aging sponsored the  
93 | most comprehensive single study of the anti-aging effects of  
94 | HGH and found marginal benefits and significant side effects.

95 |         It warned that HGH should not be widely prescribed and  
96 | should be limited to controlled research studies.

97 |         Another study, this one released in 2007 by researchers  
98 | at Stanford University, concluded that HGH cannot be  
99 | recommended as an anti-aging therapy, end quote.

100 |         Well, many athletes believe they get an edge by using  
101 | HGH, even though it is outlawed in all professional sports.  
102 | They think it can make them faster and stronger, and they  
103 | also think that it can help them heal more quickly. But  
104 | there is only limited scientific evidence to support these

105 | beliefs. In fact, according to one expert, the best way to  
106 | maximize growth hormone production is to get 8 hours of sleep  
107 | a night, not take injections.

108 |       Today, we'll hear from our experts that the increase in  
109 | muscle mass that can result from taking HGH may actually be  
110 | due to water retention. There are real risks from the  
111 | improper use of HGH. Human growth hormone can elevate blood  
112 | sugar levels and cause diabetes. It can increase  
113 | triglyceride levels in blood which can contribute to heart  
114 | disease. HGH can also result in fluid retention, which then  
115 | can cause swelling, joint and muscle pain and carpal tunnel  
116 | syndrome.

117 |       We know that HGH can cause problems, because it's  
118 | actually a disease where the body produces too much HGH.  
119 | Doctors call that disease acromegaly. It can lead to  
120 | diabetes, heart problems, liver problems, kidney problems,  
121 | cancer and even death.

122 |       It can also cause permanent changes in the face. We  
123 | know what these changes look like. The pro wrestler, Andre  
124 | the Giant, died of complications of untreated acromegaly; and  
125 | Richard Kiel, better known as Jaws from the James Bond  
126 | movies, has publicly spoken about his experience with this  
127 | disease. There are also cases where bodybuilders are  
128 | injecting such large doses of HGH that they are seeing some  
129 | of these same problems.

130           HGH purchased from the Internet may carry additional  
131 risks. It may not be made in FDA-approved plants, and it may  
132 not even be HGH. In many cases, it is contaminated with  
133 other drugs, including steroids.

134           Because of these dangers, HGH is subject to special  
135 scrutiny by the Food and Drug Administration. HGH is unique  
136 in that doctors are actually prohibited from prescribing it  
137 for any use that has not been specifically approved by the  
138 FDA. This means the doctors who are prescribing the drug to  
139 enhance performance or to reverse aging are actually breaking  
140 the law.

141           We will also focus today on the use of injectable  
142 vitamin B-12. There seems to be a widespread myth that B-12  
143 injections can increase energy, fight off colds and generally  
144 promote good health. The reality is that B-12 injections are  
145 useful for those who suffer from pernicious anemia or have  
146 difficulty absorbing B-12 from their food or B-12 tablets.  
147 For everyone else, injectable B-12 appears to be an  
148 unnecessary needle and a waste of money.

149           When we began our investigation into steroids in  
150 baseball 3 years ago, the committee's primary focus was the  
151 health of teenagers who emulate their sports heroes. That  
152 remains our focus, and that's why this hearing is so  
153 important. But, beyond teenagers, we have these widespread  
154 myths that are leading others to use these drugs and wasting

155 | their money and may be jeopardizing their health.

156 |       I want to thank our witnesses for being here today, and  
157 | I look forward to their testimony. I will introduce them in  
158 | a minute. But I want to call on Ranking Member Tom Davis for  
159 | his opening statement.

160 |       [Prepared statement of Chairman Waxman follows:]

161 | \*\*\*\*\* INSERT 1-X \*\*\*\*\*

162 Mr. DAVIS OF VIRGINIA. Mr. Chairman, thank you very  
163 much and thank you for your leadership and holding the  
164 hearing today.

165 Athletes at all levels, from the sandlot to the Super  
166 Bowl, look for an edge, that little something extra that  
167 could mean the difference between winning and losing.  
168 Advances in training equipment and nutrition offer modern  
169 competitive paths to strength, skill and longevity not  
170 available to previous generations, but that high-pressure  
171 quest for physical prowess has also spawned a thriving  
172 subculture of claims hyping the benefits and downplaying the  
173 risks of everything from vitamin supplements to steroids.  
174 Today, we try to sort through some of those claims, focussing  
175 our discussion on two substances much in the news lately,  
176 human growth hormone, HGH, and vitamin B-12.

177 The committee's 3-year bipartisan investigation of  
178 performance-enhancing substance abuse in professional sports  
179 uncovered an industry dangerous and tolerant of  
180 pseudo-science and medical mysteries in its locker rooms.  
181 The Mitchell Report added to that picture, making clear that,  
182 while steroid abuse continues to be a concern, the newest  
183 trend is HGH abuse, alleged to speed recovery from injuries  
184 and building muscle mass.

185 Without question, those attempting to market or  
186 distribute HGH claiming it will aid, heal, slow or reverse

187 | the aging process, assist in weight loss or cure depression  
188 | are scamming consumers and breaking the law. These crass  
189 | moneymaking schemes play on vanity and promise scientifically  
190 | unproven results, while openly promoting unapproved uses of a  
191 | serious biological therapy.

192 |         Synthetic HGH is approved by the Food and Drug  
193 | Administration for a limited number of scientifically  
194 | supported uses: children with growth hormone deficiency;  
195 | wasting associated with HIV and AIDS; and, in rare instances,  
196 | adult growth hormone deficiency. For these indications, HGH  
197 | is an important therapy for real medical needs. But even  
198 | when used appropriately, HGH is not without possible  
199 | long-term side effects, including an increased risk of  
200 | diabetes, carpal tunnel syndrome, nerve pain, hypothyroidism,  
201 | arthritis and cancer.

202 |         No long-term clinical studies have been conducted on the  
203 | effects of HGH in healthy adults or in anyone with doses  
204 | exceeding the FDA approved levels, and those are only the  
205 | known risks associated with the abuse of real HGH. Even the  
206 | quickest Internet search produces countless advertisements  
207 | for nonprescription or dietary supplement HGH and pills,  
208 | sprays and topical creams. Consumers ordering these products  
209 | run the risk of putting counterfeit, contaminated or altered  
210 | substances in their bodies.

211 |         It's impossible to differentiate legitimate drugs from

212 | fakes by just looking at them. Best case, gullable people  
213 | are only being scammed out of their money; worst case, they  
214 | are placing their health in the hands of criminals who could  
215 | be operating beyond the reach of our laws anywhere in the  
216 | world.

217 |         B-12 abuse involves similar scams but admittedly fewer  
218 | risks. The vitamin is essential for normal nervous system  
219 | function and blood cell production. For most people, a  
220 | balanced diet captures adequate amounts of B-12. Injections  
221 | of additional B-12 under the supervision of a physician can  
222 | be therapeutic for patients diagnosed with a specific vitamin  
223 | deficiency or anemia. But there's no reliable evidence to  
224 | prove or even suggest B-12 injections given to healthy people  
225 | produce increased energy, aid in weight loss or improve  
226 | athletic performance. Nevertheless, Web sites, anti-aging  
227 | centers and so-called sports medicine experts continue to  
228 | flout the law and promote unproven unapproved uses for HGH,  
229 | B-12 and a variety of other products.

230 |         Hearings like this have to be but one part of a much  
231 | larger effort involving parents, coaches and health providers  
232 | to educate consumers, especially young people, about the  
233 | gauzy myths and harsher realities of HGH, B-12 and other  
234 | alleged pharmacological shortcuts to athletic success. That  
235 | in the end is what makes this oversight so important,  
236 | preventing drug abuse and other physically damaging

237 | activities by young athletes. Even tacit acquiescence by  
238 | professional sports franchises and locker room malpractice  
239 | and quackery glamorizes harmful, even illegal practices that  
240 | young impressionable aspirants are bound to mimic. In that  
241 | respect, HGH and B-12 can be seen as gateway drugs to steroid  
242 | abuse.

243 |         We have to find a way to block transmission of that  
244 | false incentive and convince young athletes there are no  
245 | magic pills or wonder drugs that will grease the path to the  
246 | hall of fame. Only hard work and the most effective antidote  
247 | to illicit drugs, the truth, should fuel the bodies and minds  
248 | of those seeking athletic excellence at any level.

249 |         Today's witnesses bring invaluable expertise to our  
250 | oversight, and we appreciate their willingness to testify. I  
251 | look forward to a frank and informative discussion of the  
252 | myths and realities of performance-enhancing drugs.

253 |         Thank you, Mr. Chairman.

254 |         Chairman WAXMAN. Thank you very much, Mr. Davis.

255 |         Our panel of witnesses today:

256 |         Dr. Susan Shurin. Dr. Shurin is the Deputy Director of  
257 | the National Institutes of Health's National Heart, Lung and  
258 | Blood Institute. She's an expert in pediatric hematology and  
259 | oncology.

260 |         Dr. Thomas Perls is an attending physician in the  
261 | geriatrics section at Boston Medical Center. He is also

262 | visiting scholar at the gerontology department at Boston  
263 | University and has published a number of peer-reviewed  
264 | articles about aging and also about anti-aging medicine.

265 |         Dr. Alan Rogol is a practicing pediatric endocrinologist  
266 | in Charlottesville, Virginia. He is also professor of  
267 | clinical pediatrics at the University of Virginia and a  
268 | professor of clinical pediatrics at the Indiana University  
269 | School of Medicine. Today, he's representing the Endocrine  
270 | Society. Among his patients are children who are being  
271 | appropriately treated with human growth hormone, and he is an  
272 | expert on the effects of HGH on children.

273 |         And Dr. Todd Schlifstein. Dr. Schlifstein practices  
274 | sports medicine in New York City and treats athletes, among  
275 | others. He is an attending physician at both the RUSK  
276 | Institute of Rehabilitation Medicine at New York University  
277 | School of Medicine and also at the Orthopedic Institute of  
278 | New York University School for Joint Disease. He is an  
279 | assistant professor at the New York University School of  
280 | Medicine.

281 |         We're pleased to have each of you here today. It's the  
282 | practice of this committee that all witnesses testify under  
283 | oath. So if you would please rise and raise your right hand.

284 |         [witnesses sworn.]

285 |         Chairman WAXMAN. Thank you.

286 |         The record will indicate that the witnesses answered in

287 | the affirmative.

288 |       Your prepared statements will be in the record in its  
289 | entirety. What we'd like to ask each of you to do is be sure  
290 | the button of the mike is pressed so that it's on and then  
291 | try to limit your oral presentation to us to around 5  
292 | minutes.

293 |       There's a little clock sitting there; and it will be  
294 | green for 4 minutes, yellow for the last minute. And when it  
295 | turns red it will indicate to you that the 5 minutes are up,  
296 | and we'd like you to then be sure to summarize your  
297 | statement.

298 | STATEMENTS OF SUSAN B. SHURIN, M.D., DEPUTY DIRECTOR,  
299 | NATIONAL HEART, LUNG AND BLOOD INSTITUTE, NATIONAL INSTITUTES  
300 | OF HEALTH; THOMAS T. PERLS, M.D., MPH, ASSOCIATE PROFESSOR OF  
301 | MEDICINE AND DIRECTOR, NEW ENGLAND CENTENARIAN STUDY, BOSTON  
302 | UNIVERSITY SCHOOL OF MEDICINE; ALAN D. ROGOL, M.D., PH.D.,  
303 | PROFESSOR OF CLINICAL PEDIATRICS, UNIVERSITY OF VIRGINIA,  
304 | PROFESSOR OF CLINICAL PEDIATRICS, INDIANA UNIVERSITY SCHOOL  
305 | OF MEDICINE, ALSO REPRESENTING THE ENDOCRINE SOCIETY; AND  
306 | TODD SCHLIFSTEIN, M.D., DEPARTMENT OF REHABILITATION  
307 | MEDICINE, HOSPITAL FOR JOINT DISEASES

308 | Chairman WAXMAN. Dr. Shurin, why don't we start with  
309 | you.

310 | STATEMENT OF SUSAN B. SHURIN, M.D.

311 | Dr. SHURIN. Mr. Chairman, members of the committee,  
312 | thank you for the opportunity to appear before you in my  
313 | capacity as Deputy Director of the National Heart, Lung and  
314 | Blood Institute, which is part of the National Institutes of  
315 | Health, an agency of the Department of Health and Human  
316 | Services. I'm here today to discuss the current state of the  
317 | science of vitamin B-12 and to briefly outline what we know

318 | about vitamin B-12 deficiency and the administration of  
319 | vitamin B-12 to healthy persons.

320 |         A vitamin is a chemical substance that is required for a  
321 | particular chemical reaction in the body but is not  
322 | synthesized by the body and therefore needs to be included in  
323 | the diet. The dietary requirements for normal function are  
324 | usually relatively small. Most vitamins that are known today  
325 | were recognized because their deficiency causes recognizable  
326 | diseases. Examples, for instance, would be scurvy, caused by  
327 | a deficiency of vitamin C, which ultimately motivated British  
328 | sailors to carry limes onboard ship, and beriberi, which is  
329 | caused by a deficiency of thiamine, or vitamin B1.

330 |         Supplemental vitamins are usually not required by people  
331 | who have varied, well-balanced diets and normal metabolism.  
332 | However, supplements are often advisable for people who are  
333 | on limited diets or have increased requirements for vitamins,  
334 | such as pregnant women and growing children. Moreover, a  
335 | number of gastrointestinal diseases can interfere with  
336 | absorption of vitamins and cause deficiencies even in people  
337 | who have adequate dietary supplies.

338 |         Vitamin B-12 is required for a number of vital biologic  
339 | reactions. Two of its most important roles are in the  
340 | production of components of DNA and in the proper functioning  
341 | of different parts of the neurologic system. Tissues in  
342 | which cells are constantly dividing, such as bone marrow and

343 | the lining of the entire gastrointestinal and respiratory  
344 | tracts, require a constant supply of vitamin B-12. Normal  
345 | function of cells throughout the nervous system and spinal  
346 | cord also requires vitamin B-12.

347 |         Vitamin B-12 comes from animal products and from  
348 | bacteria. The stomach produces a factor that binds to the  
349 | vitamin in food and allows it to be absorbed in the small  
350 | intestine. Therefore, the primary causes of vitamin B-12  
351 | deficiency are dietary deficiency and malabsorption.

352 |         Diets that lack food from animal sources tend to be low  
353 | in vitamin B-12. Strict vegans, for instance, need a source  
354 | of vitamin B-12. However, it can take 5 years for someone  
355 | with adequate stores of vitamin B-12 to develop a deficiency  
356 | after a major change in diet.

357 |         Diseases of the stomach and small intestine can cause  
358 | problems with absorption and consequent vitamin B-12  
359 | deficiency. Some people make antibodies to the cells that  
360 | produce the stomach factor which is necessary for absorption  
361 | of B-12 and therefore cannot produce the factor. As a  
362 | result, they develop a condition called pernicious anemia, to  
363 | which Representative Waxman, referred which can cause a  
364 | decrease in the number of blood cells. Extensive bowel  
365 | resections, removal of much of the stomach or inflammatory  
366 | bowel disease can also cause vitamin B-12 deficiency. In all  
367 | of these conditions, they need to be treated with monthly

368 B-12 injections, because the vitamin cannot be absorbed from  
369 food or pills without the stomach factor.

370 B-12 deficiency has several major manifestations. A  
371 very characteristic anemia, in which the red blood cells are  
372 larger than normal, may progress to include low numbers of  
373 white blood cells and platelets. The symptoms of anemia  
374 include fatigue and shortness of breath on exertion. The  
375 lining of the mouth and the gastrointestinal tract can be  
376 thin and abnormal. The neurologic symptoms are particularly  
377 serious and may be hard to recognize.

378 Difficulty with position sense, nerve damage,  
379 depression, memory loss and dementia are seen with vitamin  
380 B-12 deficiency, even when the hematologic manifestation are  
381 not obvious.

382 Recent studies have highlighted the value of screening  
383 for vitamin B-12 in older people with mild dementia. B-12  
384 deficiency in older individuals is probably related to  
385 changes in the GI tract with aging and fairly limited diets.  
386 Both problems appear to be more common with advancing age.  
387 For this reason, the 2005 Dietary Guidelines for Americans  
388 recommends that persons over 50 consume vitamin B-12 in its  
389 crystalline form, such as fortified pills or pills.  
390 Pernicious anemia is most common in older women, who must  
391 receive vitamin B-12 by injection.

392 Diagnosing mild cases in B-12 deficiency can be

393 | difficult. While looking for low B-12 levels can be useful  
394 | for diagnosis of severe deficiency, serum levels of folate,  
395 | homocysteine, methylmalonic acid, 2-methylcitric acid and  
396 | cystathionine can help make the diagnosis in milder cases.

397 |       The only medical indications for administration of  
398 | vitamin B-12 are deficiency of a vitamin or risk factors for  
399 | developing such deficiency, such as stomach or bowel disease  
400 | or a limited diet.

401 |       Some manufacturers and distributors of dietary  
402 | supplements may claim that vitamin B-12 administration will  
403 | improve energy levels, memory, concentration and mood. All  
404 | of these are true when the person has vitamin B-12 deficiency  
405 | and are treated with B-12. However, there is no evidence at  
406 | all that these clinical benefits occur when the vitamin is  
407 | given to people who are not deficient.

408 |       Vitamin B-12 is not toxic when given to nondeficient  
409 | persons. It is simply excreted in the urine. So you don't  
410 | build up your stores beyond a certain level. Administration  
411 | of vitamin B-12 does not enhance physical or cognitive  
412 | function of persons who are not B-12 deficient.

413 |       Thank you for the opportunity to provide information on  
414 | this topic. I'd be happy to answer any questions the  
415 | committee may have.

416 |       Chairman WAXMAN. Thank you very much, Dr. Shurin.  
417 | We're going to have questions after all the witnesses

418 | testify.

419 [Prepared statement of Dr. Shurin follows:]

420 \*\*\*\*\* INSERT 1-1 \*\*\*\*\*

421 Chairman WAXMAN. Dr. Perls.

422 STATEMENT OF THOMAS T. PERLS, M.D.

423 Dr. PERLS. Thank you, Chairman.

424 Chairman WAXMAN. Be sure the mike is pulled up close to  
425 you and that it's on.

426 Dr. PERLS. What is growth hormone? Human growth  
427 hormone, or HGH, is produced by a pea-sized endocrine gland  
428 near the base of the brain called the pituitary gland. Its  
429 primary utility relates to growth in the height of children.

430 What about deficiency in adults? Human growth hormone  
431 levels gradually decline in adults with minimal or no  
432 negative health consequences for the vast majority of the  
433 population with aging. The anti-aging industry, the primary  
434 pusher and seller of growth hormone in this country,  
435 advertises that normal declines of growth hormone causes  
436 decreases in strength, muscle mass, sleep and sexual  
437 performance and a long list of other attributes. They go on  
438 to claim that replenishing growth hormone to levels present  
439 at younger age stops or reverses these problems as well as  
440 aging itself. This is a ruse.

441 There are few medical conditions in adults that merit  
442 the use of growth hormone. Recognizing the potential for

443 growth hormone abuse, Congress amended the Food Drug and  
444 Cosmetic Act in the late 1980s and the early 1990s,  
445 stipulating that growth hormone can be distributed to adults  
446 for only three specific indications approved by the Secretary  
447 of Health and Human Services. These are: AIDS Wasting  
448 Syndrome, Short Bowel Syndrome and Growth Hormone Deficiency,  
449 also called Adult Growth Hormone Deficiency Syndrome.

450 Growth Hormone Deficiency is very rare, occurring at a  
451 rate of about one adult per 10,000; and the legal diagnosis  
452 requires documentation of disease, such as a cancer or trauma  
453 to the pituitary gland and a failed stimulation test.  
454 Oftentimes, Growth Hormone Deficiency is accompanied by  
455 deficiencies of other pituitary gland-produced hormones.

456 In January, 2007, the FDA released an alert reminding  
457 those that distribute growth hormone for anti-aging body  
458 building and athletic enhancement that they are doing so  
459 illegally. I have a copy of that at the end of my prepared  
460 remarks.

461 A recent Stanford University review of 31 clinical  
462 studies of growth hormone used among healthy, normal aging  
463 adults found the only benefit to be a slight increase in  
464 muscle mass. The documented negative side effects include  
465 soft tissue swelling, joint pains, carpal tunnel-like  
466 syndrome, breast enlargement and diabetes. Other side  
467 effects include liver and heart enlargement, increased

468 | pressure around the brain and high blood pressure.

469 |       In a 2002 Johns Hopkins study published in JAMA, about  
470 | 50 percent of subjects experienced side effects, primarily  
471 | joint pains; and 13 percent developed elevated blood sugar  
472 | levels or even diabetes.

473 |       Recent studies demonstrate strong associations between  
474 | growth hormone and prostate, colon and breast cancers. In  
475 | another study, investigators found that growth hormone  
476 | enhances the ability of cancer to spread. It is  
477 | theoretically possible that normal declines of growth hormone  
478 | with age may actually be protective against cancer.

479 |       Ironically, there's no credible evidence that growth  
480 | hormone substantially increases muscle strength or aerobic  
481 | exercise capacity in normal individuals.

482 |       What about the illegal and medically inappropriate  
483 | distribution of growth hormone? Since 1990, a growing  
484 | network of compounding pharmacies, anti-aging clinics and  
485 | physicians have created what some within the industry  
486 | estimate is a \$2-billion-a-year business for distributing  
487 | growth hormone--a distribution network involving hundreds of  
488 | thousands of weight training enthusiasts, practitioners and  
489 | promoters of anti-aging medicine and those who have fallen  
490 | victim to the growth hormone replacement scams.

491 |       I personally have found Web sites of 279 anti-aging  
492 | clinics that advertise growth hormone treatment and 26

493 | pharmacies or what are called "compounding pharmacies" that  
494 | distribute the drug to these clinics and sometimes directly  
495 | to users. I certainly discovered only a fraction of what  
496 | exists out there. There's a map at the end of my remarks  
497 | that spell out the number of some of these entities per  
498 | State.

499 |       Of the seized anti-aging clinic records I have reviewed  
500 | for the DEA, the average patient that first presents to the  
501 | clinic is not a person in their 60s or 70s seeking  
502 | alleviation of their age-related problems but, rather, a male  
503 | in their late 20s to mid 40s, weight training nearly daily,  
504 | in otherwise excellent health, clearly seeking anabolic  
505 | steroids and growth hormone.

506 |       In summary, one, experts in the care of patients with  
507 | growth hormone related problems clearly state that giving  
508 | growth hormone for anti-aging or age management is not  
509 | medically appropriate, particularly when weighing the  
510 | potential benefits versus risks.

511 |       In this modern day and age, we have witnessed the  
512 | re-emergence of the health and longevity salesman. Many  
513 | members of the public have been misled to believe in the  
514 | magical powers of growth hormone and, because of the  
515 | associated risks and other drugs typically sold along with  
516 | growth hormone, this is a major health problem. The  
517 | cash-only business of Web sites or clinics working closely

518 together with compounding pharmacies to turn huge profits,  
519 the national and international organizations promoting the  
520 illegal use of the drug, and drug companies turning a blind  
521 eye to how and to whom their product is distributed bear  
522 similarity to what some investigative reporters have likened  
523 to a narcotics trafficking ring.

524 Thank you.

525 Chairman WAXMAN. Thank you very much, Dr. Perls.

526 [Prepared statement of Dr. Perls follows:]

527 \*\*\*\*\* INSERT 1-2 \*\*\*\*\*

528 Chairman WAXMAN. Dr. Rogol.

529 STATEMENT OF ALAN D. ROGOL, M.D.

530 Dr. ROGOL. Good morning, Mr. Chairman and members of  
531 the committee. I am pleased that the committee has taken the  
532 time to examine this issue as hormone abuse and misuse has  
533 long been a concern to the Endocrine Society and its  
534 membership. The Endocrine Society's is the world's largest  
535 and most active professional organization of  
536 endocrinologists, representing over 14,000 members worldwide.  
537 We are dedicated to quality research, patient care and  
538 education.

539 Growth hormone is a natural hormone made by the  
540 pituitary or master gland. Once it circulates in the blood,  
541 growth hormone travels to bone, muscle and other tissues  
542 where it has many growth-promoting or anabolic effects and  
543 metabolic effects. In children, for example, growth hormone  
544 stimulates lineal growth or height. It is also important for  
545 the development of muscle and bone and the distribution of  
546 body fat throughout the body. In adults, growth hormone  
547 affects energy, muscle strength, bone health and  
548 psychological well-being. Having either too much or too  
549 little growth hormone can cause health problems.

550           The most common efficacy outcome for the use of growth  
551 hormone is an increase in linear growth. Growth hormone  
552 therapy employing replacement doses and modestly high doses  
553 is very safe. Very large databases have noticed only minimal  
554 increases in scoliosis and slipped capital femoral epiphysis,  
555 both likely due to rapid growth and can occur in any therapy  
556 that promotes rapid growth or just during normal puberty.

557           The single most serious side effect is increased  
558 intercranial pressures and visual disturbance, which usually  
559 occurs in the first month of therapy as the kidney is  
560 re--learning how to handle salt and water. Stopping growth  
561 hormone therapy for a few days and then beginning again at  
562 half dose is usually all that is necessary to combat these  
563 side effects.

564           Growth hormone is also administered by physicians to  
565 promote psychological well-being and alter body composition  
566 in adults, as Dr. Perls has mentioned.

567           Now I want to address the off-label uses of growth  
568 hormone. Off-label use usually occurs in adults in two main  
569 spheres, the anti-aging market and the body image or athletic  
570 market.

571           It should be noted that off-label use comes with  
572 increased risk. One risk factor is that most off-label users  
573 are usually unaware of the correct doses, at least for  
574 athletes, and one can only assume that the doses administered

575 | to athletes must be very much greater than those used for the  
576 | legitimate uses noted above. As I am sure you are aware,  
577 | increased doses often mean increased risk.

578 |         With increased doses one might get into the range of  
579 | acromegaly, as was mentioned. In children with growth  
580 | potential this may cause gigantism, but I am unaware of  
581 | anyone being able to take these doses--and actually pay for  
582 | them--in the athletic sphere as teenagers. It should be  
583 | noted that acromegaly is a serious disease with weak muscle  
584 | and very significant heart disease.

585 |         Perhaps the most insidious off-label use is by athletes  
586 | who are told they are receiving growth hormone but may  
587 | actually be receiving a different substance or substances.  
588 | Growth hormone is an injectable medication. Magazines and  
589 | the Internet are replete with advertisements for growth  
590 | hormone. Many of these preparations are taken orally and  
591 | cannot be the protein hormone HGH, for it is not active by  
592 | this route. Most likely, they contain amino acids, which do  
593 | release growth hormone but usually only in much larger doses  
594 | and given intravenously.

595 |         In fact, the amino acid arginine is administered as a  
596 | test for growth hormone sufficiency. Most of the releasers  
597 | are water soluble compounds and are excreted in the urine,  
598 | with the main side effect being expensive urine. Some of the  
599 | compounds purported to be growth hormone may have many

600 ingredients, including anabolic steroids or steroid  
601 precursors in unknown quantities and the entire preparation  
602 of unknown purity and with multiple safety concerns. Longer  
603 term use of this anabolic agent may promote tumor growth.

604 In addition, the vast majority of clinically  
605 administered growth hormone is made by recombinant DNA  
606 techniques and thus not from human tissue. Growth hormone  
607 made from human tissue has been largely removed from the  
608 market because of a rare but fatal disease called  
609 Creutzfeldt-Jacob. Some of the growth hormone now available  
610 clandestinely is of human origin and may carry this  
611 biological agent.

612 Also worth noting is that, as with any injectable, one  
613 is at risk for diseases of shared needles: Hepatitis and  
614 HIV/AIDS, both of which are serious and may be fatal.

615 In summary, there are a number of FDA-approved uses of  
616 growth hormone in children and adults. These do not include  
617 anti-aging or improvement in athletic performance. The  
618 larger the dose of growth hormone administered, the more  
619 likely moderate and serious side effects may occur.

620 Mr. Chairman, thank you.

621 Chairman WAXMAN. Thank you very much, Dr. Rogol.

622 [Prepared statement of Dr. Rogol follows:]

623 \*\*\*\*\* INSERT 1-3 \*\*\*\*\*

624 Chairman WAXMAN. Dr. Schlifstein.

625 STATEMENT OF TODD SCHLIFSTEIN, M.D.

626 Dr. SCHLIFSTEIN. Good morning. Thank you.

627 Not to be redundant, I'm going to focus in on the  
628 efficacy or the lack of efficacy of human growth hormone in  
629 regards to performance-enhancing ability or as a  
630 performance-enhancing drug.

631 As a performance-enhancing drug, human growth hormone is  
632 believed to increase energy, maintain or increase lean body  
633 mass, meaning the muscle-to-fat ratio in the body, help  
634 energy and muscles recover and help recover from previous  
635 injuries. It has only been shown to increase lean body mass,  
636 meaning the muscle-to-fat ratio. Studies have shown the  
637 benefits of human growth hormone healing from an injury have  
638 not been done or done well, and there's no shown benefit or  
639 efficacy of it as a healing agent for recovery from surgery  
640 and/or trauma. However, I have seen individual case evidence  
641 of that, yes.

642 When human growth hormone is used in combination with  
643 anabolic steroids, the effects of the steroids are believed  
644 to be amplified or improved. The combined use of anabolic  
645 steroids with human growth hormone together have shown

646 increased muscle mass, speed and size. However, when the  
647 human growth hormone and the steroids combined were compared  
648 to studies were just using the steroids alone, it was very  
649 similar improvements, meaning, it was a questionable benefit  
650 whether the human growth hormone added upon the anabolic  
651 steroids really didn't really improve increased muscle mass,  
652 size and speed.

653 For example, test performance enhancements really  
654 typically means a repeatable exercise activity of like a  
655 bench press which you would do and then 6 weeks later,  
656 without practicing, do it again, 6 weeks again, to see if  
657 there's any improvement benefit from beginning to end without  
658 practicing, doing that activity.

659 When human growth hormone was tested by itself and in  
660 that short interval of 6 weeks, it was not shown to improve  
661 any functional capacitants or functional benefit gained  
662 during that time period when used alone. When used with  
663 anabolic steroids, it was a benefit, but it was very similar  
664 to the amount of benefit that was gained with using the  
665 anabolic steroids by itself.

666 There are a lot of limitations in the medical literature  
667 currently available looking at human growth hormone as a  
668 performance-enhancing drug, as a healing agent. Most of  
669 these studies were looking at it only in the short term.  
670 There's no studies really looking at somebody using human

671 growth hormone in another capacity, which is looking at human  
672 growth hormone in combination with steroids, but someone who  
673 is cycling on steroids and then cycling off but still  
674 maintaining usually the human growth hormone. Meaning if  
675 they're taking both together in a cycle which could be  
676 anywhere from 6 to 12 weeks of the anabolic steroid, when  
677 completing that cycle, in order to come off that, cycling off  
678 that and then maintaining the use of the human growth  
679 hormone, the believed benefit is to hopefully help maintain  
680 or prevent loss of that muscle mass gained when using the  
681 anabolic steroid with the human growth hormone. It may delay  
682 loss of muscle mass or strength during that time period but  
683 really fails to maintain them at the same level when using  
684 the human growth with the anabolic steroid in combination.

685       As regards to healing from injuries, we know that it  
686 does have a direct effect on bone tissue and case reports of  
687 faster healing of fracture injuries with doses of human  
688 growth hormone have been out there but no clinical evidence  
689 in a study-based format. However, there was also a believed  
690 potential benefit in users of it in young athletic patients  
691 that they have more energy, which hasn't really been assessed  
692 and is difficult to measure. Improving soreness and  
693 recuperation from a workout, meaning are they able to work  
694 out better and harder because they are able to recuperate  
695 faster? And no assessment of how much soreness or prevention

696 | of lactic acid buildup and prevention of soreness and muscle  
697 | pain after a workout to allow to work out again. There's  
698 | questionable benefit from that respect as well.

699 |       Certainly the side effects of human growth hormone are  
700 | plentiful, as previously discussed; and many of these people  
701 | who were self-treating themselves and using human growth  
702 | hormone in this manner as a performance enhancer are finding  
703 | out the side effects by titrating it and then, once they get  
704 | the side effect, backing off.

705 |       We do see acute onset of carpal tunnel, large hands,  
706 | swollen hands, numbness, tingling from acute onset, meaning  
707 | they're taking too much. We do get joint pain, muscle pain,  
708 | joint swelling, enlargement of the joints, especially the  
709 | fingers and knuckles. As the bone grows and it grows wider,  
710 | as the growth plates already--and doesn't elongate anymore,  
711 | you get excessive bone growth, which is not only causing  
712 | problems in the short term but we're seeing patients with  
713 | much earlier and much more advanced degenerative or  
714 | osteoarthritis formation in these joints. The bones are  
715 | overgrowing tremendously and can't take that strain and wear  
716 | and tear.

717 |       Yes, we've seen incidences of patients with getting  
718 | elevated blood sugars and continuing elevated blood sugars  
719 | from the fact they're treating themselves with insulin in  
720 | order to get their sugars under control and, in cases,

721 turning themselves into diabetics. Quite often, on a lot of  
722 these Web sites you'll see adjunct medications, meaning  
723 medications to control side effects, sold right next to the  
724 place where they're selling the human growth hormone, where  
725 they're selling insulin, they're selling Lasix so you get rid  
726 of the excess water--it's a diuretic--painkillers for joint  
727 pain and stiffness, anti-inflammatories, pain medicine,  
728 anti-anxiety medication, and then other medication to help  
729 them wake up after sleeping well. Sleeping well is important  
730 for anyone who works out regularly, because that's when your  
731 body tends to heal more; and getting enough sleep certainly  
732 helps them maintain muscle mass as well.

733         So, with anything you inject, there's a risk of skin  
734 infection, cellulitis, abscess formation, fibrosis scar  
735 tissue, which I have seen. I have seen a lot of it. After a  
736 while, they start running out of places to inject themselves  
737 because there's so much scar tissue in there. Having to have  
738 areas resected because there's fluid collections in there,  
739 especially with anabolic steroids that are oil based because  
740 they don't dissolve. They really don't break down, and they  
741 tend to sit there and get infected chronically and have to be  
742 resected.

743         When patients are treating themselves or self-treating  
744 themselves, then they're usually using multiple poly-pharmacy  
745 techniques in order to control or limit some of the side

746 effects in order to maintain the supposed benefits of using  
747 those drugs.

748         Also, with a tremendously large fraudulent  
749 market--meaning a fake product--out there, there's a lot of  
750 other drugs that are being used in replacement of the human  
751 growth hormone that's very hard to distinguish between the  
752 two by looking at it. Most of the companies--pharmaceutical  
753 companies that produce this and legitimately produce this,  
754 you have on their Web sites ways to detect fraudulent market  
755 or fake products, because they're very hard to distinguish.  
756 They're very well done, and they're changing all the time in  
757 order to keep ahead of the market.

758         Quite often, it's HCG which is very inexpensive and easy  
759 to get. HCG is sometimes used by people who are on anabolic  
760 steroids but are tapering off a cycle. It helps simulate  
761 your body to help produce more hormones itself. So they  
762 taper off. They don't bottom out completely from having a  
763 low testosterone level. So they get a little benefit in  
764 feeling like it's working, but it's really not doing much.  
765 And then, also, it's sometimes combined with an anabolic  
766 steroid, so they really think they're getting a benefit where  
767 they're really not getting a benefit from that.

768         Chairman WAXMAN. Dr. Schlifstein, let me stop you  
769 there, because I wanted to ask some questions.

770 [Prepared statement of Dr. Schlifstein follows:]

771 \*\*\*\*\* INSERT 1-4 \*\*\*\*\*

772 Chairman WAXMAN. I wanted to start the questions for  
773 the 5 minutes that each member will have.

774 We pay a lot of attention on steroids because steroids  
775 does enhance performance. Isn't that accurate?

776 Dr. SCHLIFSTEIN. Yes, that's an accurate statement.

777 Chairman WAXMAN. But it has very dangerous side  
778 effects. And we know that, if children use it, it can even  
779 cause psychiatric problems as well as other medical problems.

780 There's also a test. So if an athlete is using a steroid,  
781 it can be detected in the urine.

782 Human growth hormone, on the other hand, cannot be  
783 detected by any tests that we know of at the present time.  
784 Isn't that accurate?

785 Dr. SCHLIFSTEIN. Yes. At the present time, there's  
786 pending stuff working--

787 Chairman WAXMAN. People are working on it. But some  
788 athletes believe that if they use human growth hormone, it's  
789 going to increase their performance and they won't get  
790 caught.

791 Dr. SCHLIFSTEIN. Right.

792 Chairman WAXMAN. Are they mistaken? Does it increase  
793 their performance?

794 Dr. SCHLIFSTEIN. Well, the reason it has that appeal  
795 that way is because you can't detect it; and if you are on  
796 like a steroid and you stop it, you try to falsely inflate

797 | yourself into thinking you're going to maintain the benefits  
798 | you have gotten from the steroids and hopefully make it  
799 | longer lasting. It may help a little bit in the short term,  
800 | but that effect I think will be very short lived.

801 | Chairman WAXMAN. That's a short term in conjunction  
802 | with steroids.

803 | Dr. SCHLIFSTEIN. Right. As it tapers off, you want to  
804 | try and hold onto that benefit because it's really not going  
805 | to--

806 | Chairman WAXMAN. A lot of them are using it instead of  
807 | steroids.

808 | Dr. Rogol, there is this widespread belief that using  
809 | human growth hormone can increase your muscle mass. Does it  
810 | make you faster? Does it make you stronger?

811 | Dr. ROGOL. Well, this is the second time--that's two  
812 | out of three for the Olympics: ciltius, altius and  
813 | fortius--higher stronger and faster. And the answer is,  
814 | probably not by itself. So as you look at Sylvester Stallone  
815 | and say that's a different body for a 61-year-old man, he may  
816 | very well have been taking growth hormone, Jintropin, that he  
817 | said he was taking. None of us in this room knows what else  
818 | he was taking; and I think it's the "what else", meaning  
819 | anabolic steroids, that made the difference.

820 | There is, sir, no question that there is a lipolytic,  
821 | that is, fat breakdown effect and mild anabolic effect. So

822 | if you're a bodybuilder and you want that ripped look, that  
823 | might make sense. But that's about the only place. There  
824 | are no studies of people who are honest-to-goodness growth  
825 | hormone deficient given growth hormone legitimately that  
826 | shows that their strength is very much better and certainly  
827 | no performance data, sir.

828 | Chairman WAXMAN. Well, some people believe it's going  
829 | to make them more ripped and stronger and faster and more  
830 | able to perform. What risks are they taking?

831 | Dr. ROGOL. Well, if you are an adult--most of them have  
832 | been mentioned by the two gentlemen who flank me. The major  
833 | risks are, first of all, early on, the edema, muscle aches,  
834 | joint aches. And remember, sir, these are anabolic hormones.

835 | They lead to the production of insulin-like growth factor  
836 | one, IGF-1, which is really pro growth of tumors. So the  
837 | aging population, whether it's men like we are and prostate  
838 | cancer or women with breast cancer, harbor smaller, earlier  
839 | tumors than the older people; and this may just lead to their  
840 | growth. Theoretical to be sure. But absolutely true in  
841 | vitro. In addition, can show the effects of growth hormone  
842 | but especially IGF-1 on that particular biological effect.

843 | Chairman WAXMAN. Dr. Perls, you know a lot about human  
844 | growth hormone. If a young athlete were asking you whether  
845 | you should take it because he thinks it will increase his  
846 | muscle mass, lower his fat and help him be a better athlete,

847 | what would you say?

848 |       Dr. PERLS. Firstly, it's certainly not worth the risk;  
849 | and, secondly, you know that I would hope that he would go  
850 | about these things in an honest way. One of the dangers of  
851 | the athletes or entertainers taking this stuff is providing a  
852 | very bad example for all these young people certainly. There  
853 | are no clinical studies showing the long-term risk in terms  
854 | of cancer, but certainly short-term studies show that there  
855 | is substantial risk.

856 |       I think kind of the bigger picture is is that we have an  
857 | anti-aging industry and other areas of the market that do an  
858 | unbelievably good job of marketing an incredible false sense  
859 | of safety and an incredible false sense of tremendous  
860 | benefits from these drugs; and out of that comes a huge  
861 | amount of money, \$2 billion a year, for these hucksters.

862 |       I think that there's--you know, if you look at the  
863 | Internet, blogs where a lot of these athletes or bodybuilders  
864 | are discussing what to do in terms of the recipes and  
865 | cocktails and what have you, everybody's just kind of playing  
866 | a guessing game, saying this works, this works, this doesn't  
867 | work, don't do this because you'll get caught. It's almost  
868 | like a cult-like presence, and nobody is really like making  
869 | any decisions with the help of caring physicians like from  
870 | the Endocrine Society or elsewhere that really understand the  
871 | risks and benefits.

872 Chairman WAXMAN. They're not relying on the science;  
873 they're relying on mythology. Is that correct sir?

874 Dr. PERLS. And it's almost how much of this is placebo.  
875 Again, they're not just a danger to their bodies. It's a  
876 huge danger to their pocketbook. And a lot of the people  
877 that are taking this stuff, they're not getting the lab  
878 tests. They're not being well followed.

879 So they are really in danger of developing really  
880 significant heart disease, for example. Not so much from the  
881 growth hormone, but I very rarely have ever saw growth  
882 hormone taken in isolation. It's--you're almost always given  
883 it with a lot of other drugs, anabolic steroids, HCG,  
884 Eliminex, all kinds of drugs. So it's really amazing to me  
885 that they can take all these things. They're not getting  
886 followed by any lab tests. They're not really being followed  
887 by a physician. They're really putting themselves in  
888 significant danger.

889 Chairman WAXMAN. Thank you very much.

890 Mr. Davis.

891 Mr. ISSA. Thank you, Mr. Chairman.

892 I guess I'll start off with B-12, since that's a  
893 relatively new part of our investigation.

894 Dr. Shurin, you spoke mostly on B-12. Let me ask it, if  
895 you will, on behalf of the vitamin industry. Medical  
896 professionals thought, by and large, will tell us that

897 | the--whatever it is--several billion dollar industry, from  
898 | One a Day to every other vitamin, just gives you expensive  
899 | urine. Is that a generalization that it's pretty darn  
900 | accurate that the medical industry and the science industry  
901 | and certainly pharma tells us that there's very little  
902 | benefit to most vitamins, particularly oral?

903 |         Dr. SHURIN. Yeah. I think the shotgun approach, in  
904 | which you just give lots of vitamins because, for the most  
905 | part, more doesn't do you any harm--there are situations in  
906 | which it does. People tend to take it rather than or  
907 | figuring out how to eat a balanced diet, how to get vitamins  
908 | in the ways that are far better for their bodies.

909 |         Mr. ISSA. The medical profession tends to give  
910 | antibiotics without knowing exactly what the infection is.

911 |         Dr. SHURIN. It happens all the time, yes.

912 |         Mr. ISSA. The reason why I want to focus on that, from  
913 | a practical standpoint, B-12 is simply another vitamin that a  
914 | vast, vast number of people believe will help them.

915 |         Dr. SHURIN. Right.

916 |         Mr. ISSA. Now I happen to have a mother who, during  
917 | most of her pre-menopausal days, was getting various vitamin  
918 | B-12 supplements by injections by my own first cousin who was  
919 | a family doctor who thoroughly believed that this was  
920 | something that was helpful for her persistent anemia. He may  
921 | have been right. He may have been wrong. But I grew up with

922 | those injections.

923 |       Is there any reason for this panel to get involved in a  
924 | multibillion dollar industry and debate the merits of vitamin  
925 | supplements in general here today that would be--where we  
926 | would be effective? We have in the past weighed in, both  
927 | this committee and the chairman's other committee and my  
928 | other committee, the Energy and Commerce Committee. We have  
929 | gotten involved in the vitamin industry; and, at the end of  
930 | the day, it's still a conundrum. Would you say that is  
931 | roughly correct?

932 |       Dr. SHURIN. Yeah.

933 |       There are several issues here. One is that many of the  
934 | vitamins--certainly, the evolution of discovery of these  
935 | vitamins is people gave cocktails, like all the B vitamins  
936 | sort of came together, and so you could only give them  
937 | together. And then, as you've dissected out, we now have a  
938 | lot more components. So it's a common practice for many  
939 | older practitioners to give these sort of cocktails.

940 |       The biggest danger for situations in which they're given  
941 | without a clear understanding of what you are giving them for  
942 | is you may not--if you actually have a problem, is you may  
943 | not be making the underlying diagnosis.

944 |       For instance, one of the common situations as you are  
945 | describing with your mother is that the person may have a  
946 | mild hematologic disease, such as beta thalassemia minor,

947 | which is an inherited blood disease that doesn't get better  
948 | no matter what you give. And the biggest problem is that  
949 | there's an anxiety that's associated with it because I've got  
950 | anemia and is that--does that mean that there's something  
951 | serious?

952 |         The vitamins themselves generally don't hurt. Excess  
953 | iron, of course, can hurt.

954 |         I would say that the major damage that's done is the  
955 | failure to diagnosis and to treat significant problems and  
956 | then just the costs.

957 |         Mr. ISSA. Okay. And because so much of our hearings  
958 | have focused on athletics, I'm going to assume for today that  
959 | the taking of vitamins by athletes of all levels probably is  
960 | so benign as to not be a major part of what we should be  
961 | looking into today. Rather, steroids and human growth  
962 | hormone are. Which brings up a real point that I'd like to  
963 | make in the remaining time.

964 |         It appears as though this committee's good work under  
965 | both the chairman and ranking member have led to professional  
966 | and amateur athletics doing testings for steroids, and I  
967 | think that we should all be very proud that that's happened  
968 | and happened without legislation. However, it appears that  
969 | since there's no test for human growth hormone and it appears  
970 | as though there is a legitimate--I'm going to rephrase  
971 | that--there is a reason that people would think that it works

972 | as part of an ongoing attempt to evade detection, that we  
973 | need--this committee needs to look at the development of a  
974 | test for human growth hormone, perhaps federally funded.

975 |         And, last, if--and anyone can answer that  
976 | disagrees--whether Sylvester Stallone, Jesse Ventura, Arnold  
977 | Schwarzenegger or Hulk Hogan--two of whom became governors.  
978 | It appears as though there is, unfortunately, a tendency for  
979 | the good-looking body on the runway to be part of both  
980 | steroids and human growth hormone; and, up until now, we  
981 | really haven't, as a committee, attacked that. Because,  
982 | basically, looking good on the runway, looking good running  
983 | for--well, the chairman looking good running for re-election  
984 | in Hollywood and Los Angeles has not--and he does look good,  
985 | and he does get elected by a wide margin with Hollywood and  
986 | Beverly Hills--

987 |         Chairman WAXMAN. It ain't my looks.

988 |         Mr. ISSA. It could just be the physique, though.

989 |         But if you would comment on the fact that, as of right  
990 | now, that has not been successfully looked at. In other  
991 | words, outside of athletics, we're not presently testing; and  
992 | we do have at least two governors who had incredibly  
993 | good-looking bodies that may have contributed to their  
994 | election.

995 |         Chairman WAXMAN. The gentleman's time is up, but let's  
996 | see if the panel wants to answer any of these points.

997 Dr. ROGOL. In full disclosure, I'm working with both  
998 USADA and WADA on the growth hormone testing. There's  
999 certain things I can say; there's certain things I can't.

1000 Mr. ISSA. We can keep a secret.

1001 Dr. ROGOL. Yeah, right. Is this the IRS?

1002 It is a blood test, first of all, number one; and,  
1003 number two, so there are a lot of difficulties with labor  
1004 contracts, what you're allowed to do and what you're not.  
1005 There are some very good tests in the urine that prove you  
1006 can't find HGH in the urine. So while there are no tests  
1007 that are presently available that will show HGH use beyond a  
1008 couple of weeks, there indeed are tests and they are in the  
1009 mill that pass the International Olympic Committee's  
1010 standards, sir.

1011 Chairman WAXMAN. Thank you very much.

1012 Dr. Perls, you wanted to make a quick comment.

1013 Dr. PERLS. Another interesting idea would be to compel  
1014 the pharmaceutical companies to add some kind of inert marker  
1015 to the drug so that it does absolutely nothing in terms of  
1016 biological activity, but it would be easy to detect. This  
1017 could be with growth hormone. It could be with anabolic  
1018 steroids and so on. That would be a little difficult to  
1019 compel Chinese makers of the growth hormone, but, hopefully,  
1020 the government has other ways to interrupt the flow of that.  
1021 But that might be another idea to pursue.

1022 Chairman WAXMAN. Thank you.

1023 Mr. Cummings.

1024 Mr. CUMMINGS. Thank you very much, Mr. Chairman.

1025 Dr. Rogol, you know, as we sit here, we have national  
1026 surveys--and I'm sure you are familiar with them--that tell  
1027 us as many as 4 percent of high schoolers are taking anabolic  
1028 steroids and as many as 5 percent, 1 out of 20, are using  
1029 human growth hormone. A recent confidential survey of kids  
1030 in grades 8 to 12 is even more disturbing. Over half of the  
1031 kids who have used steroids said that pro athletes influence  
1032 their decision to use those drugs. Does that surprise you at  
1033 all, any of you?

1034 Dr. ROGOL. No. I've looked at the data. The data are  
1035 anywhere from 2 to even up to 12 percent. I think the issue  
1036 of HGH is not correct, and the reason is--many kids think  
1037 they're taking HGH and, when you ask them, they're taking  
1038 something by mouth. That could not be HGH. The wallet test  
1039 is probably the most difficult test for the teenage athlete  
1040 to pass. We're talking about tens of thousands of dollars  
1041 for a year. So I think the abuse of honest-to-goodness HGH  
1042 is really quite a bit lower. The steroid numbers are exactly  
1043 in the range that you mention.

1044 Mr. CUMMINGS. The fact is is that those steroids are  
1045 harming our children, though.

1046 Dr. ROGOL. I believe so, yes.

1047 Mr. CUMMINGS. And the fact is is that I think sometimes  
1048 the media concern me because they seem to think that the  
1049 committee is just showboating. And the reason why we started  
1050 these hearings from the very beginning is because we were  
1051 concerned that young men and women were taking these  
1052 substances, trying to emulate their sports heroes. And  
1053 here's the most concerning part of the survey, it's that  
1054 three of every five kids using steroids were also willing to  
1055 take it even if it shortened their life.

1056 Dr. ROGOL. Yes.

1057 Mr. CUMMINGS. That's deep.

1058 Dr. ROGOL. It is. It goes back to an athlete dying  
1059 young. It's exactly the same phenomenon. If they could win  
1060 a gold medal, they didn't care what happened 10 or 20 years  
1061 down the road. Yes, sir.

1062 Mr. CUMMINGS. Is that, Doctor, because--when we're  
1063 younger we feel like we could do anything and we--or is it  
1064 just that--are we going for the goal, are we going for the  
1065 glory, and figure when we get the glory it's okay that we  
1066 just burn out? I mean, what is that about?

1067 And is it something to do with a person just being young  
1068 and not understanding--as one of my people in my district  
1069 once said to me after they had used this kind of stuff, he  
1070 said, I used it; and he said, I can forgive myself, but my  
1071 body won't forgive me.

1072 I mean, is it that kind of thing, Doctor?

1073 Dr. ROGOL. Well I'm not sure it's--that's a very  
1074 telling comment. But, remember, we're talking about  
1075 adolescents. I deal a lot with adolescents. They are  
1076 invincible. We all were. Never mind voting yes, but we all  
1077 were.

1078 But the point is, you know, the brain isn't fully  
1079 developed; and so the executive function, the frontal lobe  
1080 part that tells you, hey, you might not want to do this  
1081 because of the consequences, isn't so developed. So you have  
1082 the push to take it and you don't have the pull back. And so  
1083 the immature--even though it's an adolescent, the immature  
1084 brain is a bad thing to have, by the way.

1085 RPTS KESTERSON

1086 DCMN ROSEN

1087 [11:00 a.m.]

1088 Mr. CUMMINGS. The immature brain says take me? Is that  
1089 what you are saying?

1090 Dr. ROGOL. Yes. This is Alice in Wonderland.

1091 Mr. CUMMINGS. All right. That's all right. And then  
1092 the immature brain also says, hey, you know, we're doing  
1093 pretty good, let's not go backwards. Is that--

1094 Dr. ROGOL. Well, I don't know about let's not go  
1095 backwards. Let's not look forwards is probably a better way  
1096 of saying it, Mr. Cummings.

1097 Mr. CUMMINGS. I got you. Now, let me just go to your  
1098 testimony. And I saw in your testimony that there is a long  
1099 list of legitimate uses for children. And some of these  
1100 diseases have names I'm not even sure how to pronounce. So  
1101 can we simplify this list by saying that growth hormones is  
1102 used for kids who are not growing enough? Is that--

1103 Dr. ROGOL. Well, that are not growing enough for  
1104 reasons that are stated here. Kids who are caloric deficient  
1105 also don't grow well. Growth hormone would not be an  
1106 appropriate drug. So it is not growing well or normally and  
1107 having one of these conditions. In double blind trials or at  
1108 least in legitimate trials, the FDA has approved the use of  
1109 growth hormone in these conditions, most of which are rare as

1110 | can be.

1111 |       Mr. CUMMINGS. And--I mean--and when you say rare as can  
1112 | be, can you give me some numbers? I'm trying to figure out  
1113 | if somebody would be using these things and--

1114 |       Dr. ROGOL. Growth hormone deficiency is about 1 in  
1115 | 4,000; chronic kidney disease is probably about the same.  
1116 | Turner Syndrome is 1 in 2,500 girls. Small for gestational  
1117 | infants who fail to catch up to normal growth is probably 1  
1118 | in 5,000. Prader-Willi is more like 1 in 15,000. Idiopathic  
1119 | short stature is the bottom 1 percent. So it is a 1 out of  
1120 | every 100 of us. SHOX haploinsufficiency is a gene problem.  
1121 | That is about 1 in 4 or 5,000. Noonan syndrome is about the  
1122 | same. On average, between 1 in 4,000 and 1 in 10,000, sir.

1123 |       Mr. CUMMINGS. Thank you, Mr. Chairman.

1124 |       Chairman WAXMAN. Thank you, Mr. Cummings. Mr. Bilbray.

1125 |       Mr. DAVIS OF VIRGINIA. Let me go next. Thank you.

1126 | Thank you all for being here today. I think this sheds a lot  
1127 | of light on the situation. One of the difficulties is even  
1128 | if you think HGH and B-12 can do the job, with this mail  
1129 | order stuff, you're not sure what you are getting. Isn't  
1130 | that one of the problems? It is a huge problem, isn't it?  
1131 | And so contaminants get into the system very, very quickly.  
1132 | I'm trying to look at this B-12 problem.

1133 |       This has come up before this committee before. We had a  
1134 | situation a year ago where--or a couple of years ago where

1135 | one of the ball players tested positive for steroids, and he  
1136 | thought he was getting a B-12 injection. This seems to be  
1137 | fairly commonplace where athletes get B-12 injections and  
1138 | thinks it can do something. We talked--are there any adverse  
1139 | effects of getting a B-12 shot, Dr. Shurin?

1140 |         Dr. SHURIN. No, there really are not.

1141 |         Mr. DAVIS OF VIRGINIA. It is, like, drinking too much  
1142 | V-8 or something like that?

1143 |         Dr. SHURIN. Pretty much, pretty much. And there is  
1144 | absolutely no interference in the assays for B-12 and  
1145 | steroids, because one of the things that is implied by some  
1146 | of this is, as well, if I weren't--it gave you a false  
1147 | positive test for steroids or any--or other substances. That  
1148 | actually is not--is not possible. Now, many of these  
1149 | substances are coming in through tested and legitimate  
1150 | sources, and it is anybody's guess.

1151 |         Mr. DAVIS OF VIRGINIA. So again, the problem with B-12,  
1152 | particularly through the mail is you don't know what your' e  
1153 | getting. It is not FDA regulated or anything else.

1154 |         Dr. SHURIN. That's correct. If you're really getting  
1155 | B-12, it is not--it is not harmful.

1156 |         Mr. DAVIS OF VIRGINIA. Have any of you ever encountered  
1157 | a situation or a patient or known patients who thought they  
1158 | were getting one drug through the mail, particularly a B-12  
1159 | or HGH, and ended up getting something that was contaminated?

1160 Dr. SCHLIFSTEIN. Absolutely. I've tested it. It was  
1161 HGC and an anabolic steroid combined in a powder that looked  
1162 identical to the human growth hormone.

1163 Mr. DAVIS OF VIRGINIA. And would it have been harmful  
1164 if somebody injected it, do you think?

1165 Dr. SCHLIFSTEIN. Well, if someone thought they were  
1166 getting human growth hormone, it would have an effect but it  
1167 wouldn't be the effect from the human growth hormone, it  
1168 would be the effect of the anabolic steroid combined with the  
1169 HGC, which would enhance it somewhat.

1170 Dr. ROGOL. And if you were a woman, it would be much  
1171 worse.

1172 Dr. SCHLIFSTEIN. Absolutely, absolutely. If a  
1173 woman--if she thought she was getting that, that could have  
1174 dramatic secondary sex characteristics, deepening of her  
1175 voice, facial hair, excessive weight gain, hair loss, acne.  
1176 Or--I had a woman whose husband was buying steroids on line  
1177 and didn't tell her. They went away on vacation, he put his  
1178 pills in her sleeping pill bottle. She took them for a week  
1179 thinking they were sleeping pills and in a week she grew  
1180 facial hair, a beard, deepened voice, gained 15 pounds, acne,  
1181 clitoral hypertrophy just from one week. 6 months later, it  
1182 still never reversed itself. 25 years old. Just by taking  
1183 it accidentally for a week.

1184 Mr. DAVIS OF VIRGINIA. So this stuff is dangerous?

1185 Mr. SCHLIFSTEIN. Yep.

1186 Mr. DAVIS OF VIRGINIA. On the HGH side, we talked a  
1187 little bit about some of the side effects from using  
1188 that--not just contaminated, but using regular human growth  
1189 hormone. There are a large and a growing number of Web sites  
1190 marketing HGH injections. How do you respond to proponents  
1191 of HGH that believe it is a safe alternative to steroids? Go  
1192 ahead, Dr. Perls.

1193 Dr. PERLS. There are thousands of Web sites. You put  
1194 in human growth hormone or HGH and antiaging into Google and  
1195 you get somewhere in the range of a million, 500,000 hits.  
1196 And I'm not so sure they market it as an alternative to  
1197 growth hormones, they just--I mean, to steroids. It is just  
1198 a--it is the greatest thing since sliced bread. I mean, it  
1199 is really snake oil. It is the fountain of youth. And they  
1200 push this to the hilt.

1201 In terms of the medical records that I reviewed for the  
1202 DEA, I almost, however, never saw a growth hormone given in  
1203 isolation. I think the reason for this is because the  
1204 clients would never see much of any benefit and they'd wonder  
1205 where is my \$1,000 a month going. And so they see the growth  
1206 hormone combined with all these other drugs that we've been  
1207 talking about. Just--the other very interesting thing that I  
1208 saw with these clinics is that the compounding pharmacies

1209 | were, in fact, giving the growth hormone with B-12. They  
1210 | would write a prescription that said somatropin and B-12.  
1211 | And the only reason that I can think of for them doing this  
1212 | is trying to get around the law a little bit because giving  
1213 | growth hormone for antiaging, athletic use or bodybuilding is  
1214 | illegal. There is no such thing as legal off-label use. The  
1215 | Secretary of Health and Human Services says that in adults,  
1216 | it can only be used for three purposes. Maybe the  
1217 | compounding pharmacies are trying to skirt around the law a  
1218 | little bit by saying, well, we're doing very individualized  
1219 | therapy, we're trying to produce something that is  
1220 | individualized for that specific patient. But it does not  
1221 | get around the fact that that patient has requested it in the  
1222 | setting of an antiaging clinic.

1223 | Mr. DAVIS OF VIRGINIA. Thank you.

1224 | Chairman WAXMAN. Thank you, Mr. Davis. Mr. Tierney.

1225 | Mr. TIERNEY. Thank you, Mr. Chairman. Just so I--the  
1226 | human growth hormone doesn't really do anything for  
1227 | performance enhancement taken alone, correct?

1228 | Dr. ROGOL. As far as studies have gone, I'll let my  
1229 | partners say more. As far as studies have gone, no. But  
1230 | remember for those of us who do remember when the anabolic  
1231 | steroids came back, we as physicians were the worst actors of  
1232 | all. We said steroids did nothing and then there were some  
1233 | proper double blind studies done by Dr. Baseen, who is at

1234 | your institution and they do work. So there are no studies  
1235 | that show unequivocally or not even really equivocally.

1236 |         Dr. SCHLIFSTEIN. I think also the studies that are  
1237 | available don't look at it in the way it was intended to be  
1238 | used, meaning they are looking at taking that in isolation by  
1239 | itself, testing before and testing after to see if there is a  
1240 | change in performance. And that is not really its intended  
1241 | use by its users, meaning its users in conjunction with  
1242 | something else.

1243 |         Mr. TIERNEY. Like the steroids?

1244 |         Dr. SCHLIFSTEIN. Right. To maintain hopefully that  
1245 | benefit from that amount of steroid, to amplify the effect  
1246 | later on in the steroid. And when you're off the steroid,  
1247 | hopefully to maintain those benefits. And it really wasn't  
1248 | looked at in that way. Also it really wasn't looked at in  
1249 | how it effects the individual performance, meaning are you  
1250 | able to tolerate more of a workout, are you able to tolerate  
1251 | more muscle recuperation from that. Just like something like  
1252 | creatine, which is an acid buffer, it allows you work out  
1253 | more because you can tolerate more lactic acid buildup, that  
1254 | allows you to tolerate more working out, working out sooner.  
1255 | That has a benefit in the longer term, but immediately by  
1256 | itself nothing.

1257 |         Mr. TIERNEY. The research on the harm that it does  
1258 | seems to be a little more advance.

1259 Dr. SCHLIFSTEIN. Absolutely.

1260 Mr. TIERNEY. Now, all these advertisements we've seen  
1261 about people aging, this is going to reverse the aging  
1262 process, this is the fountain of youth on that basis. Even  
1263 some well-named actors trying to indicate to people--anybody  
1264 over 40 should take it. And they indicate in those  
1265 advertisements that they believe HGH actually causes aging.  
1266 It doesn't cause aging, does it, Dr. Perls?

1267 Dr. PERLS. I can speak to that. They claim that growth  
1268 hormone levels drop with aging, which is true, and therefore  
1269 the growth hormone causes aging. Aging is caused by multiple  
1270 problems involving our--hits to our DNA, our cells, chronic  
1271 damage to many different entities of our body by free  
1272 radicals and so on. It is not caused by declines in growth  
1273 hormone or other substances.

1274 Mr. TIERNEY. Does it do anything beneficial  
1275 to--regarding aging at all?

1276 Dr. PERLS. Say again?

1277 Mr. TIERNEY. Does it do anything beneficial regarding  
1278 aging?

1279 Dr. PERLS. In fact, my guess is that it does bad things  
1280 with regard to aging. Studies and lower organisms in mine  
1281 show that animals that are deficient in growth hormone  
1282 actually live 30 to 40 percent longer. These animals also  
1283 have a marketedly reduced rates of cancer. So it is

1284 | actually--probably does the opposite effect.

1285 |       Mr. TIERNEY. It sounds to me from your testimony  
1286 | earlier that the concerns we have with respect to women using  
1287 | HGH is even more pronounced than with males using it. Is  
1288 | that also correct?

1289 |       Dr. PERLS. I'm not so sure--there are other hormones  
1290 | that some of these antiaging clinics--you know, the clinics  
1291 | make their bucks on what they call hormone replacement  
1292 | programs. And it is multiple hormones from steroids  
1293 | and--which are basically testosterone or variations of--and  
1294 | growth hormone. And it is really the anabolic steroids where  
1295 | we see the untoward effects with--in women in particular.

1296 |       Mr. TIERNEY. All right. And you announced the problems  
1297 | for women using HGH earlier and I won't go over--you keep  
1298 | shaking your head, Doctor. Am I getting it wrong?

1299 |       Dr. ROGOL. What my colleague to the left mentioned were  
1300 | the problems with steroids in women, not with HGH. That is  
1301 | why I was shaking my head.

1302 |       Mr. TIERNEY. Are there any problems with women, in  
1303 | particular, using HGH?

1304 |       Dr. SCHLIFSTEIN. As compared to men differentiating, I  
1305 | haven't seen any sexual differences between one and the  
1306 | other.

1307 |       Mr. TIERNEY. So whatever problems exist for men taking  
1308 | it, it would be for women as well?

1309 Dr. SCHLIFSTEIN. Right. I mean, with testosterone, the  
1310 women's receptor is like 100 times more sensitive than the  
1311 males. So even a low dose of something that is testosterone  
1312 can have much amplified effects in women that may not reverse  
1313 themselves even if taken off. And that is an anabolic  
1314 steroid. That is not human growth hormone.

1315 Dr. PERLS. One concern would be the 1 out of 9 women  
1316 that go on to develop breast cancer and taking growth hormone  
1317 for any woman. When you're looking at that kind of  
1318 prevalence would probably be a very bad idea. And there are  
1319 studies to show that--particularly with a breast cancer  
1320 tumor, that one of the events to allow that breast cancer to  
1321 spread is when it starts expressing its own growth hormone.  
1322 So this is just a really bad idea.

1323 Mr. TIERNEY. Well, thank you. I yield back, Mr.  
1324 Chairman.

1325 Chairman WAXMAN. Thank you very much, Mr. Tierney. Mr.  
1326 Bilbray.

1327 Mr. BILBRAY. Yes. Todd, in your testimony, you were  
1328 talking about taking--administering which substance after  
1329 doing a bench press?

1330 Dr. SCHLIFSTEIN. That is one of the typical tests you  
1331 do for performance enhancement. There were studies looking  
1332 at the efficacy of human growth hormone used in combination  
1333 with anabolic steroids versus anabolic steroids by themselves

1334 and looking at that at day 1 and then day 6. There was a  
1335 slight benefit from using the human growth hormone when used  
1336 with the anabolic steroid as compared to just using the  
1337 anabolic steroid. So in that scenario, when combined with an  
1338 antibiotic steroid, it did have some performance enhancing  
1339 effect. Not in isolation, only when used with a combination  
1340 with something else.

1341 Mr. BILBRAY. The growth hormone itself, you stated that  
1342 after the workout, the administration of the substance after  
1343 a period of time, there was no net difference between the  
1344 application of the growth hormone and not--and without it?

1345 Dr. SCHLIFSTEIN. Right. When just looking at pure  
1346 performance enhancing assessment from day 1 to day--you know,  
1347 week 6, growth hormone was nothing. There was no benefit in  
1348 a test of pure performance enhancing in that time frame.

1349 Mr. BILBRAY. Doctor, I think any, you know, sophomore  
1350 in high school would tell that you if he is an athlete, that  
1351 that is not--they'd perceive that not being worth the paper  
1352 it is written on because they're exercising, working out at  
1353 least 3 days a week. They are going through extensive weight  
1354 training. And the perception would be, then, do we do these  
1355 tests showing that the use of the hormone or--during regular  
1356 training sessions where at least 3 times a week there is  
1357 extensive workout, you know, strain to the muscle mass, do we  
1358 do that kind of real world testing that these kids are

1359 | perceiving that they are going to go through?

1360 |       Dr. SCHLIFSTEIN. That's why I said I really don't think  
1361 | there is testing appropriate to what we're really looking for  
1362 | the potential benefit of. It is looking at a benefit in the  
1363 | short term. And anyone who takes it will tell you that is a  
1364 | more longer term benefit. And even by itself or potentiated  
1365 | by something else. So I don't know if that assessment tool  
1366 | really applies to that by itself is really applicable. And  
1367 | not to draw too many conclusions by that, just by saying in  
1368 | the short term.

1369 |       Mr. BILBRAY. I'm glad to say that you have brought that  
1370 | up, because I think that is really critical. Because when we  
1371 | bring data forward to persuade young people to stay off this  
1372 | stuff, we need to make sure we have a credible argument that  
1373 | they will accept. And I don't think any of my kids would  
1374 | look at this and say, yeah, dad, of course if you're not  
1375 | working out, you're not going to get any benefit from--you  
1376 | know, this is a supplement to a major workout program, so it  
1377 | has to be real life.

1378 |       So I just hope that when--we're really careful that when  
1379 | we give the argument why kids should stay away from this, it  
1380 | is one that is very defensible, it is not able to be assailed  
1381 | or justified. I--the flip side is I kind of tell them, look,  
1382 | you're working out anyways, you're going to put muscle mass  
1383 | on and, yeah, there might be a placebo effect. But until we

1384 do those kind of real world testing, our ability to sort of  
1385 argue the point is diminished to some degree. These kids are  
1386 not idiots. The fact is they may be getting into this drug  
1387 and that is stupid. But still, as I said, the--some parts of  
1388 the brain haven't developed but other parts are very well  
1389 developed.

1390 And we have to make sure that we approach this with an  
1391 intelligent argument. Because once our arguments get  
1392 debunked, then we're really in trouble trying to give science  
1393 to these kids. That is within the guy that is pushing the  
1394 drugs, pushing the substance really is saying, see, they're  
1395 really not giving the data and here is the argument. There  
1396 is already enough bad propaganda out there already. I just  
1397 hope that we have the substance--I mean, have the substance  
1398 in our argument.

1399 Do we--are we testing real life application? Do we have  
1400 that data so we can show these young people, look, here is an  
1401 athlete working out here and here is the application over  
1402 here, this is your life? Because any high school/college  
1403 student is going to tell you, you know, doing one sets of  
1404 bench presses, taking the injections and then waiting for a  
1405 month is not my world. I'm working out three times a week  
1406 extensively and I'm just looking for something that will give  
1407 me that little edge. I'm not talking about a silver bullet  
1408 that is going to do it all for me. Do we have the ability to

1409 | give them that kind of information?

1410 |         Dr. SCHLIFSTEIN. I mean, I think we have the ability to  
1411 | give them certainly the downside, the side effects. I don't  
1412 | know if we have enough ammunition to be convincing by itself.

1413 | I think that would be a little more difficult. But  
1414 | certainly it makes it more difficult when you have other  
1415 | people endorsing it by using it and saying they are using it.

1416 | And so it makes it that much harder for your argument to say  
1417 | and this doesn't work. But someone else is saying I'm using  
1418 | it like that is very hard to counterproduct, especially for a  
1419 | kid who is not looking at long-term side effects, they're  
1420 | going to get arthritis or diabetes later. He is looking at  
1421 | the short term.

1422 |         Mr. BILBRAY. All of us will admit that the statement,  
1423 | if I knew I was going to last this long, I would have taken  
1424 | better care of myself. So the universe will turn. And so,  
1425 | Mr. Chairman, I just hope that we--again, the fact is that  
1426 | they are not in a position to make the best judgments of  
1427 | anybody in the world and then they've got the ambition of  
1428 | success, which we all can suffer from. And then I just hope  
1429 | that we give them a lot more data than just this could hurt  
1430 | you when you're an old guy. Their attitude is I could  
1431 | give--I'm not looking forward to that. That's--how many  
1432 | young people do we still see smoking cigarettes. And when,  
1433 | you know, my God, if we can't get them off cigarettes, this

1434 is a hard argument to make. Thank you very much, Mr.  
1435 Chairman.

1436 Chairman WAXMAN. Thank you, Mr. Bilbray.

1437 Mr. Lynch.

1438 Mr. LYNCH. Thank you, Mr. Chairman. I want to thank  
1439 the ranking member as well. Following up--and I want to  
1440 thank our panelists for helping us out with this issue.  
1441 Following up on Mr. Bilbray's line of questioning, we have a  
1442 hearing tomorrow regarding Major League Baseball, which HGH  
1443 is an important issue and a significant danger in itself.  
1444 But I think the hearing tomorrow has provided added focus.  
1445 It has provided some context, I believe. And I think in a  
1446 way the problems in baseball, are, I think, instructive as to  
1447 the wider problem in society.

1448 In baseball, we had a situation where--let's take  
1449 steroids for example. Major League Baseball came back and  
1450 they had a greater awareness program, a greater  
1451 acknowledgement that steroids were bad. And that was--that  
1452 was right up front and a big part of their push. They came  
1453 up with a very aggressive testing program for steroids and a  
1454 very thorough testing protocol for steroids. They had much  
1455 stronger penalties for steroids. And as a result in the  
1456 Mitchell Report, it reported that steroid use in baseball was  
1457 down significantly. When they addressed the HGH or failed to  
1458 address the HGH problem, Major League Baseball, they had

1459 | no--there was reluctance to put in any testing protocol  
1460 | regarding HGH, there was not the same message put out there  
1461 | on the street that HGH is bad. And not surprisingly as a  
1462 | result, the report indicated that HGH use was on the rise.  
1463 | Now, if you look at the problem that we're having that you  
1464 | have described already where the message is not out there  
1465 | among our young people, it is not out there in the public.  
1466 | There is a very mixed message because you've got some of  
1467 | these athletes and sports figures--well, Stallone, the actor,  
1468 | there saying HGH is good. There is a real problem with  
1469 | the--I say popular opinion regarding HGH.

1470 |         And it even comes to our laws. Our laws under Title III  
1471 | of the controlled substance act include steroids. It has  
1472 | very strong criminal penalties for mere possession of  
1473 | steroids without a position--without a prescription. We have  
1474 | no prohibition for simple possession of HGH. There is no  
1475 | criminal penalty for that. And that is what I'm getting at.  
1476 | That is something we here in Congress can control. And since  
1477 | you're the experts on this and--you know, if I could just,  
1478 | you know, personally thank Dr. Perls for your good work at  
1479 | Boston Medical Center and at Boston University, what do you  
1480 | think about the idea of including HGH in Title III to include  
1481 | all of these penalties to at least legislatively send out the  
1482 | signal that this is a seriously dangerous substance?

1483 |         Dr. PERLS. I'm incredibly appreciative to the committee

1484 having this hearing in the first place to start to--not to  
1485 start to, but to look at growth hormone and the public health  
1486 concern that it represents. And along with that, stiffer  
1487 penalties such as making Schedule III, I think, is an  
1488 excellent idea. Already there are very important laws on the  
1489 books to go after the distributors for illegally  
1490 distributing--for distributing growth hormone for legal uses  
1491 that include imprisonment and fines. But adding it as a  
1492 Schedule III has all kinds of great potential in terms of  
1493 educating physicians as well. Because right now I think it  
1494 is a little fuzzy for a lot of doctors out there in terms of  
1495 what the law really is.

1496         So I think that is also very important. Along with  
1497 making it a Schedule III, though, I think it is very  
1498 important to also do what Congress can to provide additional  
1499 resources to the DEA in particular, who is short on staff and  
1500 already has to pay a lot of attention to methamphetamines and  
1501 heroin and other big drugs and this will be one more on their  
1502 list.

1503         So giving them the additional resources that they need  
1504 to carry out their mission would be very important. The  
1505 other thing, I think, is while you're at it, there are other  
1506 hormones that go along with growth hormone. There is  
1507 something called growth hormone, stimulating hormone, and  
1508 then there is the already mentioned insulin growth factors.

1509 | And as we've seen with other drugs, when one becomes hard to  
1510 | get, everybody starts looking out for one that is easy to get  
1511 | and is less expensive. When growth hormone--when things  
1512 | clamp down heavy on growth hormone, they'll start looking at  
1513 | growth hormone stimulating hormone and insulin growth factor,  
1514 | which are all part of the same endocrine access. And I would  
1515 | think it would be good to add those to the list as well.

1516 |         Mr. LYNCH. Mr. Chairman, if I can ask, I have a letter  
1517 | to me but it is actually testimony to me from Gary Wadler,  
1518 | from the World Antidoping Agency that I would just ask to be  
1519 | included in the record if I may.

1520 |         Chairman WAXMAN. Without objection, it will be  
1521 | included.

1522 |         [The information follows:]

1523 | \*\*\*\*\* INSERT 1-5 \*\*\*\*\*

1524 Mr. LYNCH. Thank you, Mr. Chairman.

1525 Chairman WAXMAN. Thank you. Mr. Sarbanes.

1526 Mr. SARBANES. Thank you, Mr. Chairman. I've learned a  
1527 ton here today, so I appreciate your holding the hearing.

1528 And I thank you for your testimony. What percentage of the  
1529 people that are using HGH or B-12 would you say are using it  
1530 exclusively without it being used in combination with  
1531 anything else? Do you have any sense of what that would be?

1532 Dr. ROGOL. No, sir.

1533 Dr. PERLS. So my exposure to this comes again from  
1534 reviewing seized medical records for the DEA from three  
1535 antiaging clinics. And I can't think of any instance where  
1536 the growth hormone B-12 was used in isolation. It's--they  
1537 were always given with anabolic steroids and a number of  
1538 other substances. And while we were talking about vitamins,  
1539 I must also say that they were providing very expensive  
1540 collections of a whole bunch of different vitamins, all on  
1541 the idea of just making a lot of money.

1542 Mr. SARBANES. So the adults in this equation have  
1543 figured out that HGH by itself and B-12 by itself and other  
1544 sort of vitamin supplements by themselves really are pretty  
1545 useless for the goals they have it sounds like.

1546 Dr. PERLS. The adults--well, I think it is the--it is  
1547 the antiaging physicians, the owners of these clinics and the  
1548 compounding pharmacies that are selling this stuff that have

1549 realized that selling it in isolation is going to make for  
1550 some angry clients and that it is probably best to get this  
1551 stuff in combination with other things. So that they try to  
1552 see some--whatever benefit that might be. And that is all  
1553 without saying much about the side effects I might add.

1554 Mr. SARBANES. Are they being explicit in the  
1555 blogosphere about the fact that the--the discussion on the  
1556 blogosphere, is it explicit about the fact that, you know, it  
1557 is the combination of steroid use with a growth hormone or  
1558 vitamin supplement--

1559 Dr. PERLS. Absolutely. Very explicit. It is amazing  
1560 following these blogs how much time everybody is spending on  
1561 what the right recipes and cocktails are and what works for  
1562 whom.

1563 Mr. SARBANES. So it still gets us back to the steroid  
1564 use as being--that is the driver? I mean, that is the  
1565 aspiration, is through that you enhance performance and these  
1566 other things are sort of on the margin to help boost the  
1567 effects of that?

1568 Dr. PERLS. I think that is right. And I also--again,  
1569 as was just intimated, this is not any kind of standard  
1570 clinical trial. This is a bunch of nonscientists,  
1571 nonclinicians just trying to feel their way through this and  
1572 saying, oh, this worked for me and this worked--and without  
1573 really any--monitoring for any long-term side effects or

1574 | benefits for that matter.

1575 |         Mr. SARBANES. How much complicity does--without  
1576 | assuming it, how much complicity would you say there has to  
1577 | be on the part of medical professionals to help perception?  
1578 | In other words, if all of those who have the science at their  
1579 | disposal were emphatic on the point of the dangers that are  
1580 | involved with steroid use or the fact that B-12 or HGH really  
1581 | doesn't help you do anything, then you would imagine that  
1582 | would be a significant deterrent to the use. But the high  
1583 | incidence of use suggests that there is some--some  
1584 | complicity. And I'm wondering--

1585 |         Dr. PERLS. In terms of the--in terms of the physicians  
1586 | who are illegally writing prescriptions for hormone and  
1587 | steroids without ever seeing the patients or the owners and  
1588 | the physicians of the antiaging clinics, it is not a matter  
1589 | of complicity. They are the driving force.

1590 |         Mr. SARBANES. Okay. And I'm running out of time. So  
1591 | let me ask you this question. I raised this in another  
1592 | hearing we had, but now I've got some experts in front of me  
1593 | and I'd be curious on your perspective on this. I bought my  
1594 | son one of these pushup kits. Okay? So it has got some  
1595 | equipment with it and it has got a video on how to use it.  
1596 | And then at the end of the video, lo and behold, it shows you  
1597 | two bottles of some kind of thing that you're supposed to  
1598 | take in conjunction with this regimen. What would that have

1599 | been most likely do you think?

1600 |         Dr. ROGOL. Hell of good marketing. That is terrific  
1601 | marketing. My guess would be if I had to guess would be  
1602 | something like HGH, but there would be a releaser or it would  
1603 | be something that you'd take by mouth that is likely  
1604 | something that is relatively harmless except to your wallet.

1605 |         Mr. SARBANES. Okay. Thank you.

1606 |         Dr. ROGOL. But that is purely a guess, Mr. Sarbanes.

1607 |         Mr. SARBANES. Understood.

1608 |         Chairman WAXMAN. Thank you, Mr. Sarbanes.

1609 |         Mr. SARBANES. He is not going to be using it anyway.

1610 |         Dr. ROGOL. Is that for the record, sir?

1611 |         Chairman WAXMAN. Ms. Watson.

1612 |         Ms. WATSON. Thank you so much, Mr. Chairman, for having  
1613 | this hearing and to the doctors who are witnesses. We  
1614 | certainly appreciate you appearing before the committee to  
1615 | let us know about some of the threats to public health. I  
1616 | want to just probe a little bit and I think most of you have  
1617 | addressed the overuse of HGH. And I know there are a couple  
1618 | of conditions that occur normally when you have too much HGH  
1619 | in the system. And I think Dr.--I want to be sure I  
1620 | pronounce your name. Is it Schlifstein?

1621 |         Dr. SCHLIFSTEIN. Schlifstein, yes.

1622 |         Ms. WATSON. Yes. You mentioned a woman taking her  
1623 | husband's--

1624 Dr. SCHLIFSTEIN. That was anabolic steroids. It was a  
1625 steroid that she took by mistake.

1626 Ms. WATSON. Oh, I see. Okay. There is something  
1627 called acromegaly. And, of course, we know about gigantism.  
1628 And I would like any of you that can, can you describe the  
1629 problems associated with acro--what is it, acromegaly?  
1630 And--to us so we can understand it? And I see these  
1631 hearings, Mr. Chairman, as very helpful to the general public  
1632 and certainly helpful to us because we live in this drug  
1633 culture. You can't turn your TV on, you can't listen to the  
1634 radio--they are not pushing something over the counter or go  
1635 talk to your doctor about this.

1636 So I think our young people believe that the way to live  
1637 their lives and to enhance their abilities is to take some of  
1638 these drugs. Now, some of these things occur in the body  
1639 normally, so, Dr. Rogol, maybe I should start with you. Can  
1640 you describe the problems associated within acromegaly.

1641 Dr. ROGOL. I'm actually going to let Dr. Perls do it.  
1642 He is a big people's doctor. I'm a little people's doctor.

1643 Dr. PERLS. Acromegaly involves usually a tumor of the  
1644 pituitary gland where it is making too much growth hormone.  
1645 And you'll see the facial characteristics that was mentioned  
1646 with Andre the Giant, and so on where they get a bossing of  
1647 the forehead, they get an enlarged jaw, they can have an  
1648 increased incidence of certain cancerous tumors probably

1649 | because of the effect of growth hormone in the terms of the  
1650 | ability of a tumor to grow and to spread. They get troubles  
1651 | with their heart and liver in particular, because they get  
1652 | heart enlargement and liver enlargement. And that doesn't  
1653 | necessarily make for a better functioning organ.

1654 |         They get what is called insulin resistance or they can  
1655 | have elevated blood sugars and that can go on to develop to  
1656 | be diabetes. They do have shortened life spans, not  
1657 | increased life spans. And then there is all the other--you  
1658 | know, we had mentioned the enlarged hands and so on.

1659 |         Ms. WATSON. Maybe you can tell us about if you can  
1660 | extrapolate from the--from this experience and to the  
1661 | elderly. What can you extrapolate from acromegaly to the  
1662 | elderly?

1663 |         Dr. PERLS. Well, I first actually got interested in  
1664 | growth hormone because I run the New England centenarian  
1665 | study which is a large study of people who get to 100. And  
1666 | I'm a geriatrician who absolutely loves old people. And the  
1667 | very first concern for me was an antiaging industry that was  
1668 | portraying old people in a terrible light, saying that, you  
1669 | know, do you want to be demented and frail and really scaring  
1670 | the heck out of a very important population, the baby boom  
1671 | population, 70 million strong individuals who are very  
1672 | actively aging right now and just to scare them and then say,  
1673 | oh, by the way, we have the cure.

1674           And that would be growth hormone, books like Stop the  
1675 Clock, Reverse Aging Now, a huge number of Web sites  
1676 popularizing this. And much of this happened--it began with  
1677 a New England Journal of Medicine article in 1990 looking at  
1678 growth hormone and a very small sample of older men and  
1679 comparing the two with and without growth hormone and  
1680 basically--unfortunately a statement saying that it took 10  
1681 to 20 years of aging off of the person's life.

1682           The New England Journal editors have since come out  
1683 saying they rued the day that they ever allowed that  
1684 statement to happen because it led in part to a blooming of  
1685 this industry. And what really surprised me was with my  
1686 review of these charts for the antiaging clinics, was that  
1687 the vast majority of them are not older people. It is again  
1688 people in their late 20s, 30s and 40s who are going for the  
1689 kinds of things we see the testimonials of, these good  
1690 looking, strong athletic types. And I think unfortunately as  
1691 a society we're very susceptible to looking at testimonials  
1692 and taking them hook, line and sinker. But that is all this  
1693 market is based on, is testimonials and not real science.  
1694 And I'm hoping that the elderly population as you mentioned  
1695 are a relatively minor part of this very big public problem.

1696           Ms. WATSON. Thank you. Mr. Chairman, can I have a few  
1697 more minutes? I wanted to ask about vitamin B-12. Before I  
1698 get there, I wanted to address this to Dr. Rogol. Sylvester

1699 Stallone once told the Today Show that HGH was just amino  
1700 acids, just a collection of proteins. And the body--that the  
1701 body already produces. And how can 191 amino acids be all  
1702 that dangerous? And is it just amino acids?

1703 Dr. ROGOL. Ma'am, there is one problem with that. 191  
1704 amino acids probably aren't a problem. A 191 amino acids  
1705 hooked together that form a protein called HGH, that is what  
1706 the problem is. So it is a little B&A in the middle of that  
1707 to try to take these things and make a growth hormone. And I  
1708 suspect as some of you may have read in the article in last  
1709 Wednesday in USA Today that Mr. Stallone said all of this was  
1710 done by HGH. I am sure he took HGH. We are absolutely  
1711 unsure the 17 or 23 other things that he said.

1712 And as you probably also read, I was quoted as saying  
1713 exactly that in the USA Today. So, yeah, he took HGH. But,  
1714 again, with HGH and anything else--I am a clinical scientist.

1715 I know how to do experiments. The biggest issue in most  
1716 experiments, once they're properly designed, is what the dose  
1717 is. We know precisely what the dose is when we do an  
1718 experiment. These doses are way beyond that. They're taken  
1719 in a different way. And so we really don't have the idea of  
1720 how to go about testing or studying as Dr. Schlifstein has  
1721 said. So that is the long-winded answer to your question,  
1722 ma'am.

1723 Ms. WATSON. Thank you so much. And if I can shift now

1724 to injectable vitamin B-12. And, Dr. Shurin, can you tell us  
1725 just very briefly--I'm out of my first period of questioning  
1726 and into the second period. I'm almost out of time--but the  
1727 appropriate use of the injectable vitamin B-12?

1728 Dr. SHURIN. The appropriate use for the injectable  
1729 vitamin B-12 are for people who are unable to absorb the oral  
1730 form of B-12. Normally, if you have a perfectly normal gut,  
1731 you can absorb vitamin B-12 from your diet. Even people who  
1732 are strict vegans who don't take vitamin B-12 in their diet  
1733 can take supplemental vitamin B-12, which they usually do  
1734 from yeast and absorb it just fine. So it is people who have  
1735 had--who got pernicious anemia, people who have had bowel  
1736 resections, some people who have inflammatory bowel disease,  
1737 all need to get vitamin B-12 by injection, otherwise it is  
1738 perfectly appropriate and definitely safer to have it by  
1739 mouth. It is not dangerous by injection, but it is not  
1740 helpful either. It also means that there are syringes and  
1741 needles around which--whether it is the locker room or the  
1742 home is not a small issue.

1743 I think the potential secondary complications of having  
1744 needles and syringes around is not a trivial issue.

1745 Chairman WAXMAN. Thank you, Ms. Watson. I think your  
1746 time has expired.

1747 Ms. WATSON. Fair enough.

1748 Chairman WAXMAN. I want to ask--and you may want a

1749 second round. But I want to take a second round and ask some  
1750 questions of Dr. Schlifstein. Dr. Perls treats the elderly,  
1751 Dr. Rogol the children. But you've been a sports doctor and  
1752 you've dealt with athletes. In your experience with  
1753 athletes, if they use human growth hormone, are they more  
1754 likely than not to be using it in conjunction with other  
1755 drugs?

1756 Dr. SCHLIFSTEIN. They almost in every case are using it  
1757 with other drugs. There may be periods of time where they're  
1758 only taking that and cycling off something else. But  
1759 certainly it is the mainstay, is using with something else.  
1760 So that is why a lot of times these talks about human growth  
1761 hormone in isolation isn't really true or we shouldn't just  
1762 be talking about that. You have to talk in combination with  
1763 some type of anabolic steroid.

1764 Chairman WAXMAN. If an athlete tells me that he is  
1765 taking human growth hormone to heal from a sports injury, how  
1766 would you react to that? Is it credible? Is it helpful?

1767 Dr. SCHLIFSTEIN. We really don't have any proof that it  
1768 is beneficial in that manner. Certainly with its effect on  
1769 both muscle and bone tissue, one could hypothesize that--like  
1770 a fracture or something else may heal slightly faster than  
1771 one without taking it. I've seen some cases where people  
1772 have fractures, young people taking human growth hormone and  
1773 they healed a lot faster than normal. Was that the only

1774 factor involved? It was only a case report. So it is not  
1775 really scientific evidence. But possibly, yes.

1776 Chairman WAXMAN. And when an athlete uses it--these are  
1777 expensive items, this human growth hormone, \$1,000 a month,  
1778 are they taking very high doses do you expect from your  
1779 experience?

1780 Dr. SCHLIFSTEIN. From my experience with these people,  
1781 patients, what they've been taking, the dosing that some of  
1782 them would use for an HIV wasting syndrome, it can vary  
1783 between a quarter and a half of that dosing, because  
1784 sometimes they get it from those patients as well because  
1785 they know they're getting legitimate sources of it and don't  
1786 have to get a prescription themselves and they get it and  
1787 they buy it off those people who get it--

1788 Chairman WAXMAN. More than likely than not, they are  
1789 people hanging around that they tell them, just get me some  
1790 human growth hormone.

1791 Dr. SCHLIFSTEIN. Well, these people get it  
1792 automatically every month and they know they get a certain  
1793 amount. That's why I know how much they have of it based on  
1794 that dose. So it is already paid for and gotten through and  
1795 gotten regularly and they know it is a legitimate source and  
1796 a real source. And usually, it is about half that dose. But  
1797 that has dramatic effects on someone who is in their 20s and  
1798 30s, taking that large of a dose, especially with whatever

1799 else they're taking.

1800 Chairman WAXMAN. What is it that they think they're  
1801 getting when they take a vitamin B-15 shot? I mean, you  
1802 can't take it orally, so they get a shot. What do they  
1803 think--

1804 Dr. SCHLIFSTEIN. You referring to a B-12 shot?

1805 Chairman WAXMAN. Yeah.

1806 Dr. SCHLIFSTEIN. You know, I think a lot of that I  
1807 think is the placebo effect. If you're already doing so many  
1808 injections and you think you're going to get an energy boost  
1809 from it and you have something that looks like red syrup and  
1810 you think it is going to boost your energy, if you really  
1811 believe in it, yeah, what is another shot if you're already  
1812 taking, you know, 7, 10 a week anyway?

1813 Chairman WAXMAN. 10 in a week of B-12?

1814 Dr. SCHLIFSTEIN. Injections.

1815 Chairman WAXMAN. Injections of other drugs?

1816 Dr. SCHLIFSTEIN. Yeah. They are using it once or twice  
1817 a day. The anabolic steroid, depending on which one,  
1818 oil-based or water-based can be daily or twice a week. I  
1819 mean, insulin growth factor is even worse because they have  
1820 to inject it into each individual muscle. So you have to do  
1821 every muscle you worked out.

1822 Chairman WAXMAN. Is B-15 injected in the muscle?

1823 Dr. SCHLIFSTEIN. B-12 is. Usually it is an

1824 intramuscular injection, yes.

1825 Chairman WAXMAN. I see. How about lidocaine? Tell us  
1826 about lidocaine. And is it safe for a fitness trainer to  
1827 inject someone with lidocaine or is it a dangerous drug?

1828 Dr. SCHLIFSTEIN. Well, I don't think a fitness trainer  
1829 should be injecting anything or recommending anything either  
1830 on that behalf. But lidocaine is used as a local anesthetic.

1831 Now, as far as injections for pain management goes or for  
1832 treatment of an injury, very specific reasons and uses for  
1833 it. Now, it only is temporary, right? A short-lived,  
1834 short-acting anesthetic. It just numbs the area temporarily,  
1835 and in 2 hours it is gone. So if someone has an inflamed,  
1836 irritated joint, we may put some corticoid steroid, an  
1837 anti-inflammatory steroid combined with some lidocaine,  
1838 inject it into a joint to get pain relief from an inflamed,  
1839 irritated joint. The lidocaine gives them temporary  
1840 short-term pain relief, while the anti-inflammatory or  
1841 corticoid steroid or cortisone takes time to work its  
1842 anti-inflammatory effect.

1843 Now, that can be injected into a muscle, yes. Sometimes  
1844 it can be injected into a muscle usually with a corticoid  
1845 steroid or anti-inflammatory steroid as well for pain relief  
1846 into what we call a trigger point.

1847 Chairman WAXMAN. Is this a dangerous drug?

1848 Dr. SCHLIFSTEIN. It can be, depending on dose, amount

1849 and frequency. Now, usually a limited amount would be  
1850 injected and--with joint space, most of it tends to stay in  
1851 that joint space. Injected into a muscle, there is going to  
1852 be some systemic absorption.

1853 Chairman WAXMAN. Who do you think should give this kind  
1854 of injection? You say not--

1855 Dr. SCHLIFSTEIN. I mean, only a physician and I would  
1856 say only a trained physician in that specialty.

1857 Chairman WAXMAN. What specialty, sports medicine?

1858 Dr. SCHLIFSTEIN. Sports medicine or pain management,  
1859 somewhere where they know how much you're doing and where  
1860 you're doing it. You can get other effects to nerves. You  
1861 can do a nerve block by mistake, you can cause damage to that  
1862 nerve. There are a lot of other potential problems with  
1863 that. And when injecting it into a muscle, you want it just  
1864 into that muscle, you don't want to damage any other tissue.  
1865 If someone has what we call a trigger point or like back pain  
1866 and you put into the muscle spasm, it helps that muscle relax  
1867 but only temporarily.

1868 Chairman WAXMAN. My last question. Is it a performance  
1869 enhancing drug, this lidocaine.

1870 Dr. SCHLIFSTEIN. It is not a performance enhancing  
1871 drug. It is purely a local anesthetic or local pain  
1872 reliever? Any other members wish for more time? Mr.  
1873 Bilbray.

1874 Mr. BILBRAY. So lidocaine really just addresses the  
1875 pain. So it doesn't--

1876 Dr. SCHLIFSTEIN. So something wouldn't hurt.

1877 Mr. BILBRAY. I guess the only way to performance  
1878 enhancement would be to eliminate the pain so you could  
1879 continue to perform without knowing that you actually have  
1880 damage going on there and probably create more damage?

1881 Dr. SCHLIFSTEIN. Right, which is a dangerous scenario  
1882 because you're going to have an anesthetic or numb area where  
1883 you inject it. So potentially, during an athletic  
1884 competition or an event, there are serious concerns about  
1885 doing that kind of injection because you're not going to have  
1886 the normal feedback.

1887 Mr. BILBRAY. Pain tends to be nature's way of telling  
1888 us to slow down?

1889 Dr. SCHLIFSTEIN. Absolutely.

1890 Mr. BILBRAY. Okay. Well, those of us over 50 relate to  
1891 that. The B-12 image of enhancement, is that the increased  
1892 red blood cells thus the fact is that the blood is able to  
1893 carry more oxygen, able to do that? Is that the image that  
1894 is being given out on the B-12?

1895 Dr. SHURIN. That is exactly right. The benefits of  
1896 receiving B-12, if you're B-12 deficient, are all in exactly  
1897 the areas where people want to have enhanced performance.  
1898 You have more energy, your red count goes up, you have better

1899 | memory, you have better concentration, your nerves function  
1900 | better. So all of those things are clearly benefited if  
1901 | you're B-12 deficient and you get treated with vitamin B-12.  
1902 | And I think what is happening is that they are extrapolating  
1903 | from that kind of situation to the idea that if you're  
1904 | starting--

1905 |         Mr. BILBRAY. A little is good; a whole lot is better.

1906 |         Dr. SHURIN. That is exactly right. And it is very  
1907 | clear that that is, in fact, not the case.

1908 |         Dr. ROGOL. Mr. Bilbray, I think there is a little  
1909 | confusion here. Most of the athletes who want that are  
1910 | taking erythropoietin rather than B-12. And so EPO is  
1911 | another hormonal drug of abuse, and that is where medals were  
1912 | lost in Salt Lake City based on compounds like that. And so  
1913 | there is quite a difference and most of the athletes are more  
1914 | likely to take erythropoietin than they are to take B-12.

1915 |         Dr. SHURIN. B-12 use is very, very common. And I think  
1916 | what they're looking for is some of the same kind of benefit  
1917 | that they'd also look for from erythropoietin. The big  
1918 | difference is that the use of erythropoietin is not without  
1919 | major side effects. You said erythropoietin is a serious  
1920 | business and that is actually--that is the Tour de France  
1921 | problem as well.

1922 |         Mr. BILBRAY. Okay. Now, when we focus on the problems,  
1923 | the problems, the problems and trying to grasp for the

1924 | answers, one other thing that I think that those of us here  
1925 | in the Federal Government have jurisdiction specifically on  
1926 | and may be able to address is this issue of the network that  
1927 | is distributing the propaganda out to our young people which  
1928 | is not necessarily over the traditional airwaves, but over  
1929 | the new vehicle of communication for the next generation,  
1930 | that is the Internet. Was it fair to say that the Internet  
1931 | could be, you know, a major line of communication on not only  
1932 | touting this--these substances, but also the possibility of  
1933 | distributing them?

1934 |         Dr. SCHLIFSTEIN. I think it is a dangerous combination  
1935 | of both. You're getting information from the same place that  
1936 | is trying to sell you something. Of course, they're going to  
1937 | tell you the good sides or the potential good sides or even  
1938 | if they're not even truth. But the myths of it--they're  
1939 | certainly not selling you the downsides and that is the same  
1940 | source of information you use in the purchase of something  
1941 | from--which is a dangerous combination when you do the two  
1942 | together.

1943 |         Dr. PERLS. It goes beyond just individuals on the  
1944 | Internet marketing and pushing the stuff. There is  
1945 | coordinated efforts between clinicians or these clinics and  
1946 | the compounding pharmacies or a number of drug busts--Raw  
1947 | Deal was one of them. Another one is something called Witch  
1948 | Doctor--that these operations conducted by the DEA and others

1949 | that showed that there are coordinated efforts between these  
1950 | entities to push and market the stuff to go into gyms and  
1951 | sports spas to actually recruit individuals to take the drug  
1952 | and then they get a kickback for that.

1953 |         There are much larger almost pseudo medical societies  
1954 | bent around antiaging that have courses and symposia on how  
1955 | to take--how to deliver the drug, how to have successful  
1956 | antiaging practices. They produce books. They produce very  
1957 | large conventions, both nationally and internationally where  
1958 | they bring all these folks under one roof.

1959 |         Mr. BILBRAY. So you've got a whole network. And the  
1960 | Internet, though, is a major part of that?

1961 |         Dr. PERLS. Sure. Well, they have their Web sites and  
1962 | what have you--

1963 |         Mr. BILBRAY. Even among those groups?

1964 |         Dr. PERLS. The Internet is most dangerous because of  
1965 | such easy access by the--by everyone. And then--

1966 |         Mr. BILBRAY. Especially at the high-risk population?

1967 |         Dr. PERLS. Right.

1968 |         Mr. BILBRAY. Young males wanting--Mr. Chairman, I just  
1969 | wanted to raise that issue because I think that one of the  
1970 | things that we have had a success in the past working  
1971 | on--and, in fact, you and I worked on the telecommunication  
1972 | bill over the energy and commerce back in the '90s of  
1973 | addressing the use of the Internet as a predatorial vehicle

1974 on young people. I, have a feeling that we ought to be  
1975 looking at the Internet as being part of the answer to this  
1976 issue of those who are using these predatorial activities for  
1977 selling these drugs and really trying to address how we  
1978 monitor and enable to regulate the Internet to at least try  
1979 to obstruct it from being a fast track to substance abuse.  
1980 Thank you very much, Mr. Chairman.

1981 Chairman WAXMAN. Thank you, Mr. Bilbray. It would be  
1982 Mr. Lynch first if you want more time and Ms. Watson if she  
1983 wishes more time.

1984 Mr. LYNCH. Just briefly. On that same topic again. I  
1985 do know that the difficulty in policing some drugs, such as  
1986 OxyContin was that doctors--individual physicians had the  
1987 right to--to prescribe them so-called off--off labeled for  
1988 reasons and for situations that weren't necessarily the  
1989 primary reason for certain medications. Interestingly  
1990 enough, HGH is one of a very rare examples--I can think of no  
1991 other drug that we've investigated up here that has a  
1992 prohibition that says you can't prescribe this off label.  
1993 And that is what--that is what the FDA says about HGH.

1994 So all of this stuff, whether it is on the Internet or  
1995 whether it is in the mail or whether it is, you know, within  
1996 these gyms, all of this stuff is right now off label. It is  
1997 prohibited flatly by the FDA.

1998 So since--I think we already have the tools to stop

1999 | this. And I just want to know, you know, from our panelists,  
2000 | is it a matter of enforcement that we're falling down on here  
2001 | or do you think that there is some other, you know,  
2002 | prohibition maybe regarding the Internet? And I just think  
2003 | that is the vehicle--that is just one way of selling this  
2004 | stuff. I think that we have the tools already to stop this  
2005 | if we were serious about it. I'd just like to hear your  
2006 | thoughts on that.

2007 |         Dr. ROGOL. I presume that is correct if it really is  
2008 | human growth hormone. That is precisely the drug that the  
2009 | FDA talked about. But I could see the biggest amount of  
2010 | wiggle room with things that aren't HGH because they--they  
2011 | say, well, this is not proscribed. So that is where I think  
2012 | there might be a lot of difficulty because it is my  
2013 | opinion--I haven't looked at the Internet sites--but it is my  
2014 | opinion that the vast majority of the hype for this are  
2015 | things other than the 191 amino acid drug--HGH. So that  
2016 | might be another avenue to look at. It is just a little bit  
2017 | different than what you said, sir.

2018 |         Mr. LYNCH. That is very good, Doctor. That explains a  
2019 | lot. Anybody else? Dr. Perls?

2020 |         Dr. PERLS. I'd actually disagree. The amount of hype  
2021 | and literature in marketing that I've seen around growth  
2022 | hormone, the injectable is unfathomable in that it does  
2023 | represent a \$2 billion a year market for the--what we call

2024 | the off-label indications of growth hormone or the illegal  
2025 | indications. The laws are there to prevent the illegal  
2026 | distribution or to try and prevent the illegal distribution,  
2027 | but it doesn't get to possession as you have mentioned. And  
2028 | I do think that calling something a Schedule III has a great  
2029 | deal of education benefit to the people who prescribe the  
2030 | drug. There is--I think it became a big problem--it's been  
2031 | going on for about 17 years and it's been pretty much under  
2032 | the radar because it is a fairly obscure rule.

2033 |         You said it is unique and it is. So I think taking the  
2034 | extra steps to bring it out of obscurity is very important  
2035 | and a bill to make it Schedule III I think would very much  
2036 | help in that vein. And then, of course, there is providing  
2037 | the resources to go after it. I think another big problem is  
2038 | a very overstretched FDA and DEA in their ability to deal  
2039 | with all the things that they have to deal with.

2040 |         Mr. LYNCH. Okay. All right. Thank you, Mr. Chairman.  
2041 |         Chairman WAXMAN. And, Ms. Watson, do you wish to ask  
2042 | further questions?

2043 |         Ms. WATSON. Just very quickly. I wanted to raise an  
2044 | issue about lidocaine. Just recently we saw a very tragic  
2045 | news story about a young lady who was on her way, as we  
2046 | understand, to the laser hair removal clinic and spread  
2047 | lidocaine cream all over her leg, and I guess her body and  
2048 | she had a seizure, collapsed and died. Can someone comment

2049 | on the cream that you can get? And should it be controlled  
2050 | by a professional?

2051 |         Dr. ROGOL. I don't know about the cream, but I was  
2052 | going to mention before lidocaine is a drug that affects  
2053 | electrical activity, whether it is of your heart or your  
2054 | brain. So when physicians appropriately inject into a joint,  
2055 | shoulder, knee are the usual ones, no problem. But when it  
2056 | gets systemic, that is when you have the problems. And so  
2057 | cardiac and brain arrhythmias, which is, in essence, what a  
2058 | seizure is, are a known side effect of that particular drug.

2059 |         Dr. SCHLIFSTEIN. Right. It would have to be taken in  
2060 | very large quantities through the skin to be absorbed that  
2061 | way. Now, you can get it over the counter which is, like, 1  
2062 | percent. Prescription strength is 5 percent. There is also  
2063 | a topical patch which is Lidoderm, which is lidocaine in a  
2064 | patch which is 5 percent. Now, if you keep doing that, your  
2065 | body is going to absorb more and more, and eventually it will  
2066 | get into your blood stream and you'll probably build it up  
2067 | over time.

2068 |         Lidocaine is also an anti-arrhythmic. I mean, it is  
2069 | usually--to prevent a heart from having arrhythmias. But  
2070 | like any anti arrhythmic, it can be prorhythmic. And it also  
2071 | affects the electrical conductivity of your heart, and it  
2072 | certainly can affect the electrical conductivity of your  
2073 | brain. I think the perception is if it is over the counter,

2074 | or if it is a topical medication, the perception is I can't  
2075 | take too much, it won't get absorbed. There have been cases  
2076 | of people from taking the topical aspirin creams who have  
2077 | died from salicylate toxicity or aspirin toxicity just  
2078 | because they perceive it as benign. They are putting the  
2079 | patch on, they are putting the cream on. They don't think  
2080 | they're going to be affected that way. Lidocaine would have  
2081 | to be taken in pretty large quantity to be absorbed to have  
2082 | that effect.

2083 |         If you left three patches on for 24 hours a day, you'd  
2084 | only have about 1 percent absorption into your blood stream.  
2085 | So it would probably have to be a large dose and a continual  
2086 | dose to do that. But some patients, if they're given that,  
2087 | they need an instruction on how to take it appropriately.  
2088 | Just because you put more on, it doesn't mean the area is  
2089 | going to get more numb or penetrate more deeper. It really  
2090 | only works superficially. And I think people who are getting  
2091 | a procedure and want to anesthetize and someone prescribes  
2092 | that, has to give appropriation instruction on the use of  
2093 | that medication.

2094 |         Ms. WATSON. What I'd like to have clarified, how much  
2095 | is too much of the cream?

2096 |         Dr. SCHLIFSTEIN. I mean, it really has to only go on  
2097 | that area locally and it has to be on there a half hour  
2098 | beforehand. So if you were just doing your head, you just

2099 need enough to cover it. Once it is numb, it is not going to  
2100 get more numb. It's not going to go deeper. So it is really  
2101 going to--it is going to last 2 or 3 hours. That is how long  
2102 it lasts. More on is not going to make it last longer or be  
2103 more numb. Either it is anesthetized or it's not. There is  
2104 no in between. Usually--I mean, those tubes come in large  
2105 amounts, which is usually enough for weeks if not a month.  
2106 At most it should be applied twice a day because it will  
2107 stay--some are absorbed in the adipose or fat tissue on the  
2108 subcutaneous tissue. I mean, just under the skin, there will  
2109 be a little residual build up.

2110 If you continue to use it, you'll get continual build up  
2111 of additional lidocaine. So it probably wasn't a one time  
2112 use. It was probably a continual use and probably had to put  
2113 a lot of cream on it in order for that to occur. But, you  
2114 know, if you weren't instructed properly, you probably  
2115 wouldn't know any better. And if they had it ahead of time  
2116 before a procedure, someone is nervous, they are going to  
2117 keep doing it just to hopefully have less problems later.

2118 Chairman WAXMAN. Would the gentlelady yield to me?

2119 Ms. WATSON. Yes. I'm finished. Thank you so much.

2120 Chairman WAXMAN. If you heard about a professional  
2121 athlete who had a lidocaine injection, but didn't go to a  
2122 physician, what risks is that person taking?

2123 Dr. SCHLIFSTEIN. I think a lot. I think--even--a lot

2124 | of physicians wouldn't inject lidocaine without a lot of  
2125 | experience in doing it, and especially depending on what part  
2126 | of the body you're doing it into. Certainly there are nerves  
2127 | that go all over the body. Just as we talked about  
2128 | absorption from a topical, if you hit a blood vessel, it can  
2129 | be absorbed and you can have an arrhythmia or a seizure if it  
2130 | goes into a blood vessel because it will get absorbed really  
2131 | quickly.

2132 |         So, I mean, I would say only a medical doctor and only  
2133 | one really trained in doing those--and experienced in doing  
2134 | those procedures. Otherwise, that is when something that  
2135 | seems like a benign drug--but let's remember, it is a drug.  
2136 | So an injectable makes a risk of anything more dramatic.  
2137 | Absorptions to the blood where we can get a problem like that  
2138 | to occur is a real possibility.

2139 |         Chairman WAXMAN. Thank you. Well, this panel, I want  
2140 | to thank you all very much. You've done an excellent job in  
2141 | outlining the issues for us. Not just as it relates to  
2142 | professional athletes, but to the whole range of the  
2143 | population. And I think it has dispelled a lot of myths and  
2144 | it has also been very educational for us and for the American  
2145 | people. I'd like to ask unanimous consent that the record be  
2146 | held open for 2 weeks. There may be additional questions  
2147 | that we might ask you to respond to in writing.

2148 |         Mr. SHAYS. Just 30 seconds.

2149 Chairman WAXMAN. My colleague, Mr. Shays.

2150 Mr. SHAYS. Mr. Chairman, I just wanted to thank you for  
2151 holding this hearing and thank our witnesses. I know all the  
2152 questions have been asked that needed to be. But I think it  
2153 is important that you're doing this and I think it will lead  
2154 to some insights on the part of the government and some  
2155 action both on the part of the government and the private  
2156 sector and the sports community that I think ultimately will  
2157 have significant benefits. So thank you.

2158 Chairman WAXMAN. Thank you. That is certainly our hope  
2159 and we're going to work with you and others to try to achieve  
2160 that goal. Thank you very much for being here. That  
2161 concludes our hearing and we stand adjourned.

2162 [Whereupon, at 12:00 p.m., the committee was adjourned.]