Civil money penalties Ek — what do you think?

May 11, 1998

NOTE TO TOM FREEDMAN

Subject: GAO report on imported food -- Civil Money Penalties legislation

As I mentioned to you on the phone, the GAO report reiterates an earlier recommendation that FDA have the authority to fine importers and brokers who violate the FD&C Act (for example, who distribute a product into the U.S. even when FDA/Customs has told them to hold it because of safety concerns). Currently, the only fine is a revocation by Customs of their bond, which is often little or no deterrent.

We were preparing a legislative proposal to accomplish this, which normally would wind slowly through channels. But we could hurry it up if you guys believe it should be. It could be done simply through a small change in current civil money penally authority we have for pesticides in food (see attached section 303 of the Act), or a separate and broader provision re: penalties against anyone selling food in violation of the Act (see attached Sec. 415 language).

The advantage of the former (focused only on imports) is that it targets fairly outrageous behavior and may be supported by the domestic food industry. Indeed, the domestic industry may thinks it's a fairly small penalty, given that they are subject to criminal prosecution, product seizure and injunction for similar behavior. Consumer and health groups would likely support strongly.

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Bill Hubbard/FDA

officials told us any reduction in liquidated damages would have been in accordance with Customs guidelines.

FDA's lack of civil penalty authority, and its reliance on the importer's bond agreement with the Customs Service, has left it without an adequate economic deterrent to the distribution of adulterated imports for a long time. We reported in 1992 that in fiscal years 1988 through 1990, importers at four locations had distributed 336 (34 percent) of the 989 shipments found to be adulterated with pesticides. Although this rate was lower than the rates of 50 percent and 45 percent that we found in 1979 and 1988, respectively, it indicated that adulterated imports continue to be distributed to American consumers. We recommended in that report and others that FDA be given authority to issue civil penalties to violators.[19] While FDA submitted legislative proposals to grant them civil penalty authority in 1993, Congress did not pass the legislation.

CONCLUSIONS

FDA's lack of control over shipments selected for inspection leaves the system vulnerable to unscrupulous practices. Without sufficient controls, some importers (1) may falsify laboratory test results on suspect foods to obtain an FDA release, (2) sell potentially unsafe imported foods before FDA can inspect them, and (3) sell imported foods that FDA found violative and barred from entry. Further, importers' bonds are an ineffective deterrent against attempts to market contaminated products. As a result, FDA has little assurance that contaminated shipments are kept off U.S.

[19] Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, September 24, 1992) and Pesticides: Status of FDA's Efforts to Improve Import Monitoring and Enforcement (GAO/T-RCED-93-55, June 16, 1993)

§ 303(g)(2)(A) 1997 version

trolled Substances Act for the purposes of forfeiture under section 413 of such Act.

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(g)(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 519(a) or 520(f) unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 519(e) or 519(f) (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 501(a)(2)(A) which involve one or more devices which are not defective.

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402[redacted] shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B). The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.

(3)(A) A civil penalty under paragraph (1) or (2) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an oppor-

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"SEC. 415. CIVIL PENALTIES.

"(a) IN GENERAL.--

"(1) ACTS SUBJECT TO PENALTY; PENALTY AMOUNT.--Any person that commits an act that violates this Act with respect to food or the Consumer Food Safety Act of 1998 may be assessed a civil penalty by the Secretary of not more than $100,000 for each such act. Each such act and each day during which such act continues shall be a separate offense.

"(2) NOTICE AND HEARING.--No penalty shall be assessed by the Secretary under this section unless such person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

"(3) OTHER REQUIREMENTS.--The amount of such civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, degree of culpability, size and type of business, and any history of prior offenses; and may be reviewed only as provided in subsection (b).

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