FDA'S FAULTY SAFEGUARDS AGAINST CORRUPTION: CONCERNS OVER DEBARMENT USE AND AUTHORITY

"More than 15 years ago, Congress passed a law to let the FDA kick out companies and individuals from the drug industry convicted of crimes related to the FDA approval process. This staff report shows in great detail the record of weaknesses in FDA's ability and authority to carry out its duties and to protect its own integrity. When it comes to excluding the worst of the worst – convicted felons – FDA's debarment process seems to be non-existent. It is inexcusable that the FDA can't quickly debar convicted felons. In addition to bringing this problem to the administration's attention, I will introduce legislation to reduce FDA's budget when they don't enforce the law." – U.S. Rep. Joe Barton, R-Texas

MINORITY COMMITTEE STAFF REPORT

PREPARED FOR

THE HONORABLE JOE BARTON
RANKING MEMBER

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES
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I. KEY FINDINGS

During the First Session of the 110th Congress, the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, held hearings on the adequacy of Food and Drug Administration (FDA) efforts to assure the safety of the nation's drug supply. These hearings focused on the FDA's handling of a drug called Ketek. One of the issues involved how the FDA reacted to evidence obtained by FDA criminal investigators showing that one of the principal investigators had falsified data and committed criminal acts.

Given the issue of corruption in the FDA regulatory process, the Minority Staff of the Subcommittee on Oversight and Investigations examined the FDA's use of debarment authority under 21 U.S.C. § 335a that Congress established more than 15 years ago to protect the integrity of the FDA against companies or individuals convicted of crimes arising from conduct that would undermine the regulatory process.

The statute provides for two types of debarment proceedings: mandatory and permissive. Whether an individual or corporation is subject to mandatory or permissive debarment depends on whether the individual's or corporation's misconduct relates to an abbreviated, or generic, drug application; whether the individual or corporation has been convicted of a felony under Federal law, a misdemeanor under Federal law, or a felony under State law; and whether the individual's or corporation's misconduct relates to the development or approval of a drug product. Mandatory debarment may be permanent. With regard to permissive debarment, an individual or corporation may be debarred for a period not more than 5 years. During the period of debarment, whether the debarment is mandatory or permissive, companies and individuals are excluded from any activity related to the FDA regulatory process.

Over the course of its investigation, Minority Committee Staff reviewed materials from the FDA Office of Regulatory Affairs and from the FDA Office of Criminal Investigations.

Key findings from the Minority Staff's investigation include:

- The FDA in effect can only debar generic drug companies, not brand name drug companies. FDA lacks authority to debar a corporation when the misconduct by the corporation relates to a name brand drug. Under 21 U.S.C. § 335a, the FDA only has authority to debar corporations who are convicted of felonies under Federal law when their misconduct relates to an abbreviated, or generic, drug application. Thus, for example, if a generic drug company was convicted of falsifying data in an abbreviated drug application and a brand name drug company was convicted of falsifying data in a new drug application, the generic drug company could be debarred but the brand name company could not.

- Even though FDA can debar generic drug companies, after more than 15 years of debarment authority, FDA has not debarred even a single generic drug company. Some generic drug companies convicted of Federal criminal felonies that would have made them eligible for debarment are identified in this report. FDA has also limited its debarment authority to violative behavior related to product applications; thus, FDA will not debar for post-approval crimes like counterfeiting.

- Even though FDA can debar animal drug companies or individuals from animal drug companies, after more than 15 years of debarment authority, FDA has brought only one debarment action against an individual in the animal drug industry.

- FDA lacks authority to debar medical device companies or individuals involved with medical device companies who are convicted of crimes aimed at undermining the FDA regulatory process.

- In some instances, FDA has failed to pursue debarment against corporations or individuals who have submitted or assisted in the submission of drug product applications, even when the corporation or individual has been convicted of crimes that make them subject to debarment. In some instances, there was reason to believe from available evidence that these convicted criminals who should have been debarred continued to be involved in the drug industry.

- Minority Staff's review of FDA debarments shows that FDA has failed to pursue mandatory debarments against individuals in a timely manner. In some instances, FDA's efforts to institute a mandatory debarment against individuals have resulted in the notice of debarment being rescinded, because FDA did not bring the charges by the 5-year deadline provided for in 21 U.S.C. § 335a(l)(2).

- FDA has not initiated debarment proceedings against individuals in a consistent manner. Minority Staff has uncovered cases where individuals convicted of a felony related to the development or approval of a drug product

were not debarred, while other individuals with similar circumstances or convictions were debarred.

- FDA has failed to debar individuals convicted of crimes relating to misconduct before other Federal agencies.

- FDA has debarred 71 individuals over 15 years, but almost half of these people (32) were individuals involved in the generic drug scandal of the late 1980s. Over the last 5 years, FDA's debarment rate is only 2.5 per year. According to FDA's debarment list, FDA has used its permissive debarment authority only 9 times over 15 years. From FDA enforcement reports for the 3-year period (FY 2003- FY 2005), staff compiled a list of 40 individuals convicted of crimes who staff believes could have and should have been debarred by FDA. There have been no debarments since January 30, 2007, over one year ago.

- FDA is required to start the debarment process within 5 years (60 months) from the date of conviction. For debarments since January 1, 2000, FDA took over 38 months on average just to start the debarment process. In contrast, another agency, the Federal Communications Commission, took only about 8 months on average to debar individuals completely.

- FDA appears to have adopted an ad hoc approach when carrying out its responsibility to debar corporations and individuals who have engaged in misconduct relating to the approval or regulation of drug products. Further, FDA has either failed to devote, or does not have, sufficient staff and resources to review cases and issue debarment notices in a timely manner when it is required.

- FDA lacks internal guidance on the thresholds that must be met to justify permissive debarment of companies or individuals. The FDA Centers (Biologics, Drugs, and Animal Drugs) affected by debarment provisions operate independently.

II. BACKGROUND

On May 23, 1991, Representatives John Dingell, Thomas Bliley, and Henry Waxman introduced H.R. 2454, the Generic Drug Enforcement Act of 1991 (Act or GDEA). Five months later, the House of Representatives passed H.R. 2454 under suspension of the rules by a vote of 413-0. The bill was passed in the Senate, with one Senator noting that the debarment provision "gives FDA the tools that it needs to protect itself from such [bad] actors." 138 Cong. Rec. S5614 – S5616 (daily ed. April 10, 1992) (statement of Sen. Kennedy). The bill was signed into law by President George H.W. Bush on May 13, 1992. *See* P.L. 102-282.

As stated in the House Report which accompanied the Act, the purpose of the bill was "to give the Food and Drug Administration (FDA) additional authorities to act against individuals and companies that have engaged in illegal activities in connection with applications for permission to market generic drugs." The bill was the result of an investigation initiated in 1988 by the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee. That investigation showed that certain generic drug companies had paid "illegal gratuities to FDA staff members in exchange for preferential treatment" of their generic drug, or abbreviated drug, applications. In addition, the Subcommittee's investigation uncovered that some generic drug companies had tampered with drug tests submitted in support of their drug applications. The United States District Attorney for the District of Maryland brought charges against the individuals involved in the generic drug scheme. At the time of the Act's passage, 26 criminal guilty pleas and convictions were obtained. *See* H.R. Rep. 102-272 at 10-11 (1992), *reprinted in* 1992 U.S.C.C.A.N. 103 at 104-05.

The Act provides for two types of debarment, mandatory and permissive. With respect to mandatory debarment, the Act treats individuals and corporations differently. Corporations are subject to mandatory debarment if they are convicted after May 13, 1992, of a felony under Federal law for misconduct relating to the development or approval of any abbreviated, or generic, drug product. Individuals are subject to mandatory debarment if they are convicted of a felony under Federal law for misconduct relating to the development or approval of *any* drug product – not only abbreviated drug products. Further, FDA may pursue mandatory debarment against individuals who were convicted of felonies prior to May 13, 1992.

The type of mandatory debarment imposed also differs depending on whether the entity convicted is an individual or a corporation. A corporation that is convicted of a felony for misconduct relating to the development or approval of an abbreviated drug application must be debarred for a period not less than one year and not more than 10 years. *See* 21 U.S.C. § 335a(1) and (c)(2)(A)(i). If a subsequent, mandatory debarment of a corporation occurs within 10 years of a preceding mandatory debarment, the subsequent debarment of a corporation is permanent. *Id.* For individuals, mandatory debarment is permanent in the first instance. *See* 21 U.S.C. § 335a(c)(2)(A)(ii). The effect of the debarment on corporations and individuals, however, is similar: mandatory debarment prevents a corporation from submitting or assisting in the submission of an abbreviated drug application and individuals are prohibited from providing services in any capacity to another individual or a corporation with a pending drug product application. *See* 21 U.S.C. § 335a(c)(1).

Permissive debarment applies to corporations and individuals in the same way as mandatory debarment, in that corporations are eligible for permissive debarment only with respect to their misconduct relating to generic drugs, while individuals are subject to permissive debarment for misconduct relating to the development or approval or regulation of any drug product. The predicate acts that make a corporation or individual eligible for permissive debarment encompass a broader range of activity than do those for mandatory debarment. For example, a corporation is eligible for permissive debarment if it is convicted of (1) a felony under Federal law if convicted before May 13, 1992; (2) a misdemeanor under Federal law; (3) a felony under State law; or (4) of conspiracy to

commit or aiding and abetting any of those criminal offenses for conduct relating to an abbreviated drug application. *See* 21 U.S.C. § 335a(b)(2)(A)(i). In addition, a corporation may be eligible for permissive debarment if it has been convicted of a conspiracy to commit or aiding and abetting a felony under federal law for which an individual was convicted after May 13, 1992, if the Secretary finds that the conduct that was the basis for the conviction "undermine[d] the process for the regulation of drugs." 21 U.S.C. § 335a(b)(2)(A)(ii).

Like corporations, individuals are subject to permissive debarment if they are convicted of a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval of any drug product, or a felony under Federal law for conspiracy to commit or aiding and abetting a felony relating to the development or approval of a drug product. *See* 21 U.S.C. § 335a(b)(2)(B). In addition, individuals are subject to permissive debarment for three other categories of conduct. First, the Secretary may permissively debar an individual convicted of a felony involving bribery, fraud, perjury, making false statements, blackmail, extortion, or other similar crimes, even if those crimes do not relate to the development or approval of a drug product, so long as the Secretary finds that the individual has demonstrated a "pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements relating to drug products." Second, the Secretary may permissively debar an individual who has not been convicted of a crime. To do so, the Secretary must find that the individual has "materially participated" in acts that were the basis of a conviction of a felony under Federal law, a misdemeanor under Federal law, or a felony under State law for conduct relating to a drug product, or conspiring or aiding and abetting these crimes, and that the individual has demonstrated a "pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements relating to drug products." Finally, the Secretary may permissively debar a "high managerial agent" if the Secretary finds that the agent worked for an individual or corporation during the period in which the individual or corporation had committed acts for which a felony conviction was obtained, the agent had knowledge of the actions, knew the actions violated the law, and failed to take appropriate action, and the Secretary finds that the "conduct serving as the basis of conviction undermines the process for the regulation of drugs." *See* 21 U.S.C. § 335a(b)(2)(B)(i) – (iv).

A chart illustrating FDA's debarment authority is attached at Exhibit A.

Since the passage of the Generic Drug Enforcement Act in 1992, FDA has not debarred a single corporation. After more than 15 years with the Act, FDA has debarred 71 individuals (five of the permanent debarments were later terminated and one was withdrawn), but almost half of these debarments (32) occurred in about the first 2 years of the Act and involved convicted felons who figured in the generic drug scandal of the late 1980s. On average, FDA has debarred five individuals per year, but has debarred only 13 individuals in the last 5 years or an average of just over 2.5 per year. In 1999, FDA did not debar anybody. There have been no debarments since January 30, 2007, over one year. Over the 15-year history of the GDEA, FDA has imposed only 9 permissive debarments.

FDA's ad hoc approach to carrying out its debarment authority is partly to blame for its paltry enforcement record. At FDA, responsibility for handling debarments is not

centralized; rather the manner in which it is handled is left to each FDA center. Although it was signed into law over 15 years ago, FDA has never issued regulations implementing the debarment provisions in the Generic Drug Enforcement Act. Further, FDA staff confirmed that FDA has never promulgated guidance to assist its staff when making determinations about when FDA is required to impose debarment. Remarkably, the Center for Drug Evaluation and Research (CDER) has issued guidance on how to terminate, rather than impose, mandatory debarment of an individual.

Within the Centers, it does not appear as if a particular staff member or members is dedicated to reviewing debarment cases. Instead, depending on workload, a variety of staff members may review the cases as they are presented. Although FDA staff claimed that it debars in every instance where the facts of a case meet the criteria of the statute, as this report shows, FDA has failed to do so in several cases.

III. THE INVESTIGATION

Minority Committee Staff's inquiry into FDA's use of debarment proceedings grew from the Committee's investigation of FDA's review and approval of a New Drug Application (NDA) for telithromycin, or Ketek, submitted by Aventis Pharmaceuticals (Aventis) on February 28, 2000.[1]

During that investigation, Minority Committee Staff discovered that, although Dr. Anne Kirkman-Campbell, a clinical investigator in a Ketek safety trial, had been convicted of a felony under Federal law due to her misconduct in the trial, FDA did not move to debar her until almost 3 years after she had been incarcerated.[2] FDA's failure to take action in a timely manner increases the risks of criminals continuing to operate in, and undermine, the drug regulatory process. Questions already have been raised about the drug industry's level of due diligence in screening clinical researchers. For example, FDA, in its October 23, 2007, warning letter to Aventis about the conduct of the Ketek safety trial in question, cited among other violations the failure to select qualified investigators for the study. FDA pointed to the selection of a clinical investigator whose medical license was suspended. However, FDA's debarment authority is based on protecting the integrity of the regulatory process by helping prevent drug companies from hiring individuals convicted of FDA-related crimes. To the extent there is weakness in the drug industry's vetting of personnel, FDA's failure to debar is detrimental to improving industry performance in not hiring people with criminal records. FDA's inaction also harms the agency's ability to maintain public trust by the appearance of convicted felons being able to continue to be involved in the regulatory process. This is harmful to public confidence because bad actors, as a matter of law, ostensibly would be able to continue providing services to a drug company that has a pending or approved drug application before the FDA, including working in clinical trials, and to receive investigational drug products so long as FDA has not debarred them.

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[1] Ketek, an antibiotic, was submitted by Aventis for three indications: community-acquired pneumonia (CAP); acute bacterial sinusitis ("ABS"); and acute exacerbated chronic bronchitis (AECB). Aventis later merged with Sanofi-Synthelabo in August 2004, and is now known as Sanofi-Aventis.

[2] Dr. Kirkman-Campbell's case is discussed more fully in a later section of this report.

Upon learning of the Dr. Kirkman-Campbell case, Minority Staff initiated a thorough review of FDA's debarment actions. That review demonstrated that, in several instances, FDA had failed to make timely, consistent, or effective use of its debarment authority under 21 U.S.C. § 335a.

Representative Joe Barton, Ranking Member of the Committee on Energy and Commerce, and Representative Ed Whitfield, then Ranking Member of the Subcommittee on Oversight and Investigations, raised these matters to Inspector General Daniel R. Levinson of the Department of Health and Human Services in a letter dated March 22, 2007. A copy of this letter is attached at Exhibit B. Representatives Barton and Whitfield requested that the Inspector General examine certain issues relating to FDA's oversight and discipline of clinical investigators, including the reasons for delay between an individual's date of conviction and the date FDA begins debarment proceedings.

On September 21, 2007, Inspector General Levinson responded to Representatives Barton and Whitfield's letter, stating that given the Inspector General's "current body of ongoing work at FDA . . . it is unlikely that the [Office of the Inspector General] will be able to undertake any new evaluations at FDA in the next couple of months." A copy of Inspector General Levinson's letter is attached at Exhibit C.

Upon receiving Inspector General Levinson's response, Minority Staff continued its review of FDA enforcement actions. The results of this review are set forth in the sections that follow.

A. FDA Lacks Authority to Debar Companies Other Than Generic Drug Companies That Are Convicted of Felonies Under Federal Law for Conduct Relating to the Development or Approval of an FDA-Regulated Product.

As explained in Section II of this report, FDA lacks authority under 21 U.S.C. § 335a, or any other statute, to bring debarment actions against companies, other than generic drug companies, that have been convicted of felonies under Federal law for conduct relating to the development or approval of products regulated by FDA. This gap in the statute's coverage means that name-brand companies can continue to do business before FDA, including developing products and submitting applications to FDA for approval, despite engaging in misconduct that would subject them to debarment proceedings had they been a generic drug corporation or other corporation submitting a generic drug application.

Moreover, FDA's authority under the Generic Drug Enforcement Act is limited to "drug products," which FDA defines as drugs, animal drugs, exports of unapproved drugs, and biologics. *See* 18 U.S.C. § 321(dd). As devices are not included in the definition of drug product, FDA has no authority to debar a corporation or individual who is convicted of a crime for conduct relating to a medical device.[3] Similarly, FDA lacks

[3] Section 335a(m) does provide for debarment of third-party inspectors of device establishments. In the Medical Device User Fee Act and Modernization Act of 2002, P.L. 107-250, Congress provided that the

authority to debar medical device companies and individuals involved in the medical device approval process. For example, FDA was unable to take any action against SMLX Technologies Inc. (SMLX), or its officers, because SMLX produces devices and not drug products as defined by the Generic Drug Enforcement Act. SMLX filed an Investigational Device Exemption (IDE) in support of its test kit for HIV (human immunodeficiency virus) which was intended to detect HIV in human saliva. The IDE, however, contained altered or false testing data. Two SMLX corporate officers, Henry Schur and Nicolas Levandoski, were convicted of felonies in Federal court for mail fraud and submitting false or misleading information. SMLX, too, was convicted of a felony in Federal court for introducing an adulterated HIV test kit in interstate commerce. *See* FDA, "The Enforcement Story, Fiscal Year 2001."[4] Despite the fact that the company and two of its officers had submitted false or altered testing data to FDA, and sold a test kit that had not received the required approvals and was not manufactured in accordance with good manufacturing processes, FDA, as a matter of law, is unable to debar them because their misconduct related to a device, rather than a drug product.

Furthermore, the statute does not address a corporation's misconduct with respect to a drug product that occurs *after* a drug has been developed and approved. FDA, therefore, cannot use debarment to prevent a corporation that has been convicted of a felony with respect to an approved product now on the market from submitting or assisting in the submission of a new, generic drug application. The investigation of Flavine International, Inc. (Flavine) by the FDA Office of Criminal Investigations (OCI) is an example of the consequences that follow from the debarment statute's uneven coverage. In 1993, OCI initiated an investigation of the importation and distribution of bulk counterfeit drugs. At that time, adverse drug events, including deaths, hospitalizations, and disabilities, had been associated with gentamicin sulfate, a generic drug. Flavine, a broker of bulk drugs, was a subject of that investigation. Investigators determined that Flavine and its principals, Gerd Weithase, Wolf Vogel, and John Milhard, had engaged in counterfeiting bulk drugs, including those sold for use in the manufacture of human prescription generic drugs, when it had purchased gentamicin sulfate from a Chinese manufacturer and sold it to other companies. Ultimately, on March 20, 1996, Flavine, Weithase, Vogel, and Milhard pleaded guilty in Federal court to felonies relating to their misconduct in the development of generic drug products, including counts of conspiracy to commit drug counterfeiting and conspiracy to commit money laundering. *See* John Henkel, Investigators' Reports: Probe Proves Effective Against Antibiotic Smuggling Scheme, FDA Consumer, Jan. – Feb. 1998.[5] Despite the

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Secretary of Health and Human Services could accredit persons to conduct inspections of class II and III device establishments. If the accredited person is convicted of a felony for (1) knowingly failing to notify the Secretary of an unreasonable risk to public health at a device establishment; (2) knowing inclusion of false information in an inspection report; or (3) knowing failure to include material facts in an inspection report, the accredited person is eligible for debarment under 21 U.S.C. § 335a(m). The debarment period for corporations accredited to inspect device establishments is not less than one year and not more than 10 years; the debarment period for individuals is permanent.

[4] http://www.fda.gov/ora/about/enf_story/archive/2001/ch6/default.htm#cber.

[5] Available at http://www.fda.gov/FDAC/departs/2002/302_irs.html.

guilty pleas to felonies related to generic drugs, and the potential health risks posed by counterfeited gentamicin sulfate,[6] FDA debarred neither the company, Flavine, nor its principals, Weithase, Vogel, and Milhard.

On May 8, 2000, then-Chairman of the Committee on Energy and Commerce Tom Bliley wrote Jane Henney, then-Commissioner of FDA, regarding FDA's efforts with respect to counterfeit drugs and, in particular, with respect to the Flavine case, and noted that FDA had not debarred the company or its principals. *See* Letter to the Honorable Jane Henney, M.D., Commissioner, FDA, from Chairman Tom Bliley (May 8, 2000). In a response dated May 31, 2000, then-Associate Commissioner for Legislation Melinda K. Plaisier explained that FDA had not debarred Flavine, Weithase, Vogel, and Milhard because it felt that the "penalties imposed on the company and certain managers and employees" in the criminal prosecution "provided appropriate sanctions and significant deterrent to wrongdoing." In addition, Plaisier noted that "the violative behavior for which Flavine and its officials were convicted were not the types of charges related to *product applications* for which FDA normally debars companies or individuals." *Id*. (emphasis added).

FDA's rationale for its failure to debar the company, Flavine, or its principals, Weithase, Vogel, and Milhard, raises several interesting issues. First, FDA appears to argue that debarment is unnecessary because the criminal penalties are an appropriate sanction and a sufficient deterrent to future wrongdoing. While criminal penalties may serve as a deterrent, this rationale seems to ignore other reasons for debarment as stated in the House Report submitted for the Generic Drug Enforcement Act of 1992, that is, to "assist in restoring consumer confidence in generic drugs, to protect the integrity of the generic drug approval process, and to create a strong deterrent to future misconduct." H.R. Rep. 102-272 at 11 (1992), *reprinted in* 1992 U.S.C.C.A.N. 103 at 105. A final debarment order issued by FDA in the matter of Premchand Girdhari also indicates that the purpose of debarment is not merely to serve as a deterrent, but to "restrict future conduct." Premchand Girdhari; Denial of Hearing; Final Debarment Order, 65 Fed. Reg. 3454 at 3455-56 (Jan. 21, 2000). The Girdhari Order also calls into question FDA's explanation that debarment of Flavine or its principals was not necessary because the criminal case provided "appropriate sanctions." Also, the United States Court of Appeals for the Seventh Circuit in *Bae v. Shalala* recognized the remedial, rather than punitive, nature of the Act when it observed that the GDEA "can fairly be said *solely* to serve a remedial purpose." 44 F.3d 489, 493 (7th Cir. 1995). Again, given Congress' stated intent in passing the Generic Drug Enforcement Act and FDA's own rationale as set forth in debarment orders, it appears to be indisputable that the purpose of the act is remedial.

Second, FDA's rationale suggests that its authority over generic drug companies that are convicted of felonies is limited to their misconduct relating to the development and approval of a drug and does not reach misconduct that takes place *after* a drug is approved, no matter how egregious. If FDA's interpretation is correct, and it appears from the plain language of the statute that it is, the Flavine case reveals yet another gap in FDA's authority to oversee and take disciplinary action with respect to drug companies

[6] In 1999, the FDA linked toxic adverse reactions in 155 American patients to gentamicin sulfate from the same Chinese manufacturer involved in Flavine's smuggling scheme.

who are convicted of felonies relating to drug products. In contrast to its authority over corporations, FDA's authority to debar individuals who have been convicted of crimes is not restricted to their conduct relating to a drug's development or approval, but extends to an individual's conduct relating to the "regulation of a drug product," that is, the conduct after approval. 21 U.S.C. § 335a(2) and (b)(2)(B).

In addition, with respect to the individuals involved in the Flavine case, FDA appears to have ignored a basis for debarment specifically provided in the GDEA. Under the Act, FDA is authorized to debar individuals who have been convicted of felonies that do not relate to the development or approval of a drug product but which involve bribery, fraud, perjury, making false statements and similar crimes if the Secretary finds that the individual has "demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements . . . relating to drug products." 21 U.S.C. §335a(b)(2)(B)(ii). In the Flavine case, Weithase pleaded guilty to one count of conspiracy to commit drug counterfeiting and one count of conspiracy to commit money laundering, both crimes involving fraud, yet he was not debarred.[7] In fact, he continues to work in the drug industry as Chairman of Flavine, which also continues to operate as a marketing and distributing company for FDA-approved active pharmaceutical ingredients. Recently, in May 2006, Weithase and Flavine announced an expansion of its international operations in the China, Japan, and India markets. *See* Press Release, Chairman Gerd Weithase Leads Flavine Expansion, (May 5, 2006).[8] Other instances where FDA has chosen not to debar individuals who are convicted of felonies related to a drug product are described in Section III-C.

B. FDA Has Never Debarred a Generic Drug Company.

While FDA's anemic enforcement record against corporations is attributable, in part, to the statutory limitations in FDA's authority over corporations, FDA has failed to take debarment action against generic drug companies even when the factual basis for debarment clearly existed, as it did in the Bolar Pharmaceutical Company (Bolar) and Copley Pharmaceutical Inc. (Copley) cases.

As discussed previously, the impetus for the Generic Drug Enforcement Act debarment provisions was corruption in the generic drug industry. Bolar, a generic drug company based in Long Island, New York, was implicated in that scandal.

Evidence uncovered during investigations by FDA and the Subcommittee on Oversight and Investigations showed that during the late 1980s, Bolar had substituted name-brand products for its own generic product when seeking approval from FDA to distribute generic drugs, in particular, a generic antibiotic used to treat urinary infections. In addition, Bolar had created a second, fraudulent set of documents about its production processes to use during FDA inspections. As a result, FDA ordered Bolar to recall the drug because the company had tampered with the product safety tests. *See* Carol

[7] Vogel pleaded guilty to one count of smuggling and Milhard pleaded guilty to one count of misbranding.
[8] Available at http://www.free-press-release.com/news/200605/1146856035.html.

Strickland, Bolar: A Drug Company Under Seige, N.Y. Times, Oct. 15, 1989.[9] Eventually, in 1990, Bolar was forced to suspend shipment of all its generic drug products while FDA reviewed its operations to determine if there were irregularities in the data Bolar submitted for approval. *See* Warren E. Leary, Bolar Suspends Shipment of All Prescription Drugs, N.Y. Times, Feb. 9, 1990.[10] Finally, in February 1991, the company pleaded guilty to 20 criminal charges of illegally distributing adulterated generic drugs and obstructing government inquiries, and was ordered to pay $10 million in fines and withdraw all it applications for generic drugs previously approved by FDA. *See* Milt Freudenheim, Bolar Plans Guilty Plea on Generics, N.Y. Times, Feb. 28, 1991.

While Bolar is not eligible for mandatory debarment because the company's conviction occurred before May 13, 1992, Bolar was eligible for permissive debarment for its conduct in the generic drug scandal. Under 21 U.S.C. § 335a(b)(2(A), a corporation is eligible for permissive debarment if it has been convicted before May 13, 1992, of a felony under Federal law for conduct relating to the development or approval of an abbreviated drug application. Bolar clearly meets the bar for permissive debarment. Moreover, on August 27, 1993, FDA permanently debarred Robert Shulman, the co-founder, chairman, and chief executive officer of Bolar, after he pleaded guilty on November 8, 1991, to five counts of defrauding FDA in its investigation of the drug industry. *See* Robert Shulman; Debarment Order, 58 Fed. Reg. 45,340 (Aug. 27, 1993); *see also* Guilty Plea in Bolar Case, N.Y. Times, Nov. 8, 1991.[11] But, FDA took no action against the company.[12]

FDA's debarment record against generic drug companies did not improve in the Copley case. Copley, a manufacturer based in Massachusetts, made a variety of generic drugs. To produce generic drugs, company's manufacturing processes should be designed so that they consistently produce medicines that function like the corresponding name-brand drug product. Once FDA approves the generic drug product, any changes to those manufacturing processes must be reported to FDA. Copley, however, changed their production processes for four generic drugs without giving notice to FDA when the company became unable to meet the approved specifications for producing the drugs. Those drugs were potassium chloride, a prescription time-release tablet prescribed to treat potassium deficiency; procainamide, a prescription drug used to treat irregular heartbeat; brompheril, an over-the-counter antihistamine and nasal decongestant; and hydrocortisone acetate and pramoxine hydrochloride, a prescription drug for rectal inflammation. Copley also falsified the generic drug applications and manufacturing records it submitted to FDA in order to disguise the deviations in the manufacturing

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[9] Available at http://query.nytimes.com/gst/fullpage.html?res=950DE6D91E3CF936A25753C1A96F948260.

[10] Available at http://query.nytimes.com/gst/fullpage.html?res=9C0CE3D61F3FF93AA35751C0A966958260.

[11] Available at http://query.nytimes.com/gst/fullpage.html?res=9D0CE4DD1E39F93BA35752C1A967958260.

[12] In addition, in December 17, 1992, Bolar and its president, Lawrence S. Raisfield, were charged with one felony count of conspiring to fix the price of generic Dyazide, a drug used to treat hypertension or high blood pressure. *See* Press Release, United States Department of Justice, Two Drug Manufacturers and Their Presidents Charged with Price Fixing of Generic Drug (Dec. 17, 1992). Vitarine Pharmaceutical Company, another generic drug company, was also charged.

processes. *See* John Henkel, Investigators' Reports: Record Fine Imposed on Generic Drug Maker, FDA Consumer, November – December 1997.[13]

As a result of its misconduct, Copley was charged and pleaded guilty on May 28, 1997, to one count of conspiracy in Federal court and was ordered to pay $10.65 million for defrauding FDA. During Copley's sentencing, prosecutors stated that Copley's fraudulent applications were not mere "'paperwork error[s],'" and that the company "had intentionally deceived FDA." *Id*. At that time, the fine was the largest ever imposed on a drug company. According to information included in FDA Investigators' Reports published in 1996 and 1997, individuals within Copley were still under investigation and could be charged with criminal violations. *Id.*

Despite the fact that Copley's fraudulent behavior was considered intentional, and that the company pleaded guilty in May 1997 to falsifying generic drug applications, FDA never proposed to debar the company. In sharp contrast, another Federal agency, the Defense Logistics Agency, did propose to debar Copley from contracting with the government on May 1, 1998, due to its criminal conviction. *See* Copley Pharmaceutical Inc. Form 10-Q For June 30, 1998, Administrative Agreement Between The Defense Logistics Agency and Copley Pharmaceutical, Inc.[14] Ultimately, the Defense Logistics Agency did not debar Copley, but instead entered into an agreement with the company which required it to take certain measures to ensure the accuracy of its data and records. Further, Minority Staff was unable to find any evidence that individuals employed by Copley whom Copley knew were involved in the wrongdoing have ever been disqualified or debarred by FDA.

FDA's failure to take debarment action against Copley or its employees who participated in the misconduct is remarkable for many reasons. First, FDA's own Investigators' Reports allege that Copley's misconduct was not an isolated occurrence, but part of a pattern of regulatory misconduct by the company. *See* John Henkel, Investigators' Reports: Record Fine Imposed on Generic Drug Maker, FDA Consumer, November – December 1997.[15] Second, the company's misconduct was not merely a "paperwork error," as acknowledged by prosecutors. As a result of Copley's altering the manufacturing processes, the efficacy of the drugs was affected. Copley was forced to recall 55 million brompheril tablets because of a deviation in the number of pill coatings, which determines the speed in which the drug was absorbed by the body, had been affected. Third, with Copley's plea to conspiracy, the factual basis for debarment clearly existed. Finally, the FDA Investigators' Reports and information included in Copley's 10-Q statement filed on June 30, 1998, plainly indicate that individuals within Copley participated in the wrongdoing, yet no evidence was found of any action taken to disqualify or debar these individuals. These individuals, therefore, remain free to work with Copley or any other drug company and continue to do business before the FDA.

Unfortunately, the Copley case is not the only example where FDA failed to take debarment action against a company and its officials who provided false information to FDA. According to an FDA publication compiled by the Office of Criminal

[13] Available at http://www.fda.gov/FDAC/departs/1997/797_irs.html.
[14] Available at http://www.secinfo.com/dPaHc.76.d.htm.
[15] Available at http://www.fda.gov/FDAC/departs/1997/797_irs.html.

Investigations, "The Enforcement Story," Biochimica OPOS ("Biochimica"), like Flavine, was a manufacturer of bulk active pharmaceutical ingredients. Biochimica submitted false information and reports to FDA regarding the location and procedures of its manufacturing processes for the drug Cefaclor, an antibiotic, as well as other drug products. Specifically, Biochimica contracted out to another company the manufacture of two drug intermediates and substituted a chemical in Cefaclor with another, unapproved chemical. The investigation found that Biochimica's President and Chief Executive Officer Luigi Ratti had directed the creation of false records for submission to FDA. Ultimately, on October 19, 2001, Biochimica and its parent company, Aventis, pleaded guilty to one count of conspiracy under 18 U.S.C. § 371. Ratti was convicted on May 22, 2005, of introducing an unapproved drug into interstate commerce and sentenced to one month and 2 days incarceration and ordered to pay a criminal fine of over $16 million. *See* FDA, Office of Criminal Investigations, "The Enforcement Story, Fiscal Year 2005," at 31.[16]

FDA's failure to pursue debarment against the individuals at Copley and Biochimica who perpetrated frauds on FDA is especially troubling when FDA took action in a similar case at the same time the Copley case was pending. On March 24, 1993, Scott Feuer pleaded guilty to one count of conspiracy under 18 U.S.C. § 371 for "directing others to change manufacturing procedures for the generic drug Fenoprophen, falsifying records in order to conceal from the FDA the manufacturing changes, and distributing the Fenoprophen without FDA approval," the same conduct at issue in the Copley case. Scott Feuer; Final Debarment Order, 63 Fed. Reg. 31,789 (June 10, 1998).[17] FDA proposed permissive debarment of 5 years on March 2, 1998, and the final debarment order against Feuer was issued on June 10, 1998.[18]

While FDA's authority to debar corporations is limited by the language of the Generic Drug Enforcement Act, its enforcement record in the Copley and Biochimica cases raises questions about why FDA did not take advantage of the authority it does have under the statute to pursue companies who have been convicted of felonies under Federal law for misconduct relating to generic drug applications.

C. FDA Has Failed to Bring Debarment Actions Against Individuals Who Have Been Convicted of Crimes Relating to the Development or Approval of a Drug Product or the Regulation of a Drug Product.

In addition to FDA's decision not to debar Gerd Weithase of Flavine, FDA's own debarment list, disqualification list, and documents are replete with examples of cases where FDA has failed to pursue debarments against individuals in several different cases when the factual predicates for debarment clearly exist. For example, from the FDA

[16] Available at http://www.fda.gov/ora/about/enf_story2005_archive/ch6/default.pdf.
[17] Available at http://www.fda.gov/ora/compliance_ref/debar/dbarfedreg/feuer98.txt.
[18] FDA imposed a permissive debarment in the Feuer case even though a mandatory debarment appears to be required under 21 U.S.C. § 335a because Feuer was convicted of a felony "relating to the regulation of any drug product." It is not clear from publicly available documents why FDA elected to pursue permissive, rather than mandatory, debarment against Feuer.

enforcement reports for a 3-year period (FY 2003 – FY 2005), Minority Staff compiled a list of 40 individuals who could have been and should have been debarred, shown in a chart found at Exhibit D.

While it is troubling that FDA has failed to take action in numerous cases where debarment was required by statute, even more disturbing is that FDA's administration seems inconsistent. In several instances, individuals whose cases had similar fact patterns and who were convicted of crimes that made them eligible for debarment were treated differently by FDA. From the information available to Minority Staff, it is difficult to reconcile these cases, where the FDA did not debar individuals, with similar cases where FDA pursued debarment. Synopses of these cases, as well as cases where FDA took no action, are set forth below.

1. The Sawaya Case

The Federal conviction of Dr. Mary (Marty) Sawaya in 2004 for providing false statements to FDA is a prime example of FDA's failure to take enforcement action against individuals who have engaged in misconduct with respect to drug products. Sawaya, who conducted clinical drug studies, had done so without a medical license and had provided at least two false medical licenses to FDA as part of Investigational New Drug (IND) applications. *See* FDA, Office of Criminal Investigations, "The Enforcement Story, Fiscal Year 2004," at 10-11, available at http://www.fda.gov/ora/about/enf_story2004_archive/ch6/default.pdf. In the Office of Criminal Investigations (OCI) Fiscal Year 2004 report, OCI states that, as a result of her conviction, Sawaya was sentenced to 24 months probation and "disqualified from participating in any clinical drug study." *Id.*

Despite stating that she was disqualified in the OCI report, Minority Staff was unable to find any mention of Sawaya's disqualification in FDA's disqualification list, debarment list, or other FDA documents. Further, Minority Staff uncovered other evidence which suggests that Sawaya actively continues to practice medicine and conduct clinical research. In 2004, just one month after Sawaya pleaded guilty to making false statements, she moderated a talk on hair loss on www.hairlosstalk.com. In the summer of 2006, she spoke at a meeting of the Pearl Network, an organization of practitioners engaged in clinical research. In a pamphlet from the meeting, Sawaya is described as "speak[ing] at the closing session about past successful outcomes of [Practice-Based Research Network] research." Pearl Network, Inaugural Annual Meeting Brochure, April 22-23, 2006, available at http://pub.emmes.com/study/pearl/newsletters/summer2006.pdf. Finally, Sawaya's biography is listed at www.hairloss-research.org, a site that claims to be maintained by an organization named MPB Research. Her biography states that "Dr. Sawaya's *current clinical research* is...focused on cutaneous cancers.. and malignant melanoma." *Id.*

If Sawaya's biography is accurate and up-to-date, there is reason to believe that she is continuing to participate in clinical trials despite being convicted for making false statements to FDA in IND submissions. FDA's failure to initiate debarment proceedings

is baffling, given that the requirements for mandatory debarment are clearly met. Further, FDA's decision not to pursue debarment contradicts the purpose of the Generic Drug Enforcement Act: to restrict future conduct and bolster public confidence in drug safety.

2. The Hinkson Case

The David Hinkson case is yet another example of FDA's failure to initiate debarment proceedings. Hinkson operated a business, Water Oz, that sold mineral waters that Hinkson claimed could treat a variety of illnesses, including AIDS, cancer, alcoholism, bipolar disorder, and carpal tunnel syndrome. The water was treated with lithium, molybdenum, tin, and selenium. Ultimately, Hinkson admitted guilt to two felonies under Federal law relating to drug products: failure to label his water a drug, as required by law, and operating a facility not licensed to manufacture drugs. Hinkson also was convicted for soliciting the murders of a Federal judge, Federal prosecutor, and IRS agent who tried the Federal criminal tax charges relating to Hinkson's water business. *See* FDA, Office of Criminal Investigations, "The Enforcement Story, Fiscal Year 2005," at 6;[19] and Press Release, United States Department of Justice, Hinkson Found Guilty on Tax Charges; Water Oz Founder Also Admits Product Violations (May 5, 2004).[20]

Although Hinkson admitted his guilt with respect to misconduct relating to a drug product, and was convicted of soliciting the murder of three Federal officials and is currently incarcerated on those charges, FDA never debarred him. Without question, the factual basis for mandatory debarment exists, as Hinkson pleaded guilty to felonies under Federal law relating to the regulation of a drug product. Even if Hinkson had not been convicted of the charges relating to the labeling of his mineral water, the convictions for soliciting murder could make him eligible for permissive debarment under 21 U.S.C. § 335a(b)(2)(B)(ii)(I), as these crimes involve the obstruction of an investigation or prosecution of an offense. Yet, FDA never debarred Hinkson.

3. The Stratton Veterans Affairs Medical Center Cancer Trials Cases

Another case in which FDA has failed to initiate debarment proceedings relates to the corrupt cancer trials at Stratton Veterans Affairs Medical Center in Albany, New York. During those trials, a researcher, Paul H. Kornak, sometimes posed as a physician and altered medical records and enrolled patients in a study who did not meet the study's qualifications. One patient, Mr. Carl M. Steubing, a decorated veteran of the Battle of the Bulge who was diagnosed with gastroesophageal cancer, enrolled in the study. After participating in aggressive chemotherapy treatments as part of the trial, Mr. Steubing became violently ill and died in March 2002. *See* Deborah Sontag, In Harm's Way: Abuses Endangered Veterans in Cancer Drug Experiments, N.Y. Times, Feb. 6, 2005.[21]

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[19] Available at http://www.fda.gov/ora/about/enf_story2005_archive/ch6/default.pdf.
[20] Available at http://healthfraud.org/tx/news/aloe.htm.
[21] Available at http://www.nytimes.com/2005/02/06/nyregion/06vets.html?_r=1&oref=slogin.

Another veteran and study participant, James DiGeorgio, also died following treatment. Kornak pleaded guilty to making false statements, mail fraud, and, with respect to Mr. DiGeorgio's death, criminally negligent homicide. During his plea, Kornak also admitted that he had improperly enrolled Steubing in the study. Kornak was ultimately debarred by the Office of Research Integrity in the Department of Health and Human Services under debarment procedures relating to facilities that receive Federal funding. *See* Paul H. Kornak; Debarment Order, 71 Fed. Reg. 9555 (Feb. 24, 2006).

However, Kornak's supervisor in the clinical trials, Dr. James A. Holland, has never been debarred. FDA issued a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain Letter (NIDPOE) to Kornak's supervisor, Dr. James A. Holland, in September 2004 with respect to his conduct in the Stratton trials. *See* Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) Letter from FDA to James A. Holland, M.D. (Sept. 22, 2004).[22] The NIDPOE letter to Dr. Holland stated that Dr. Holland had failed to personally conduct or supervise the clinical investigations; failed to protect the rights, safety, and welfare of study subjects; repeatedly or deliberately submitted false information to the study sponsor; failed to ensure that the study was conducted according to protocols; and failed to maintain adequate case histories and data on the study subjects. *Id.* Almost 3 years later, Dr. Holland pleaded guilty on April 24, 2007, to a misdemeanor under Federal law for failing to establish and maintain adequate and accurate case histories on patients participating in drug studies. *See* Brendan J. Lyons, Court Papers Detail Dark Chapter at VA, Albany Times Union, Dec. 9, 2007.[23] However, Minority Staff has not been able to find any evidence showing that Dr. Holland has been debarred, although his conviction and his conduct clearly make him eligible for permissive debarment under 21 U.S.C. § 335a(b)(2)(B)(i)(I).

4. The Borison and Diamond Case

The case involving Dr. Bruce I. Diamond and Dr. Richard L. Borison, professors on the faculty of the Medical College of Georgia, is an example of FDA's disparate treatment of individuals subject to debarment.

Dr. Borison was Chairman of the Department of Psychiatry and Health Behavior at the Medical College of Georgia; Dr. Diamond was a pharmacologist. Dr. Borison and Dr. Diamond conducted clinical studies, including human trials, for name-brand drug companies on drugs to treat mental illnesses, including Alzheimer's and Schizophrenia. Contrary to the terms of their employment, however, Doctors Borison and Diamond did not seek the permission of the Medical College of Georgia to conduct these trials. In addition, Borison and Diamond "fostered the appearance" that the Medical College of Georgia supported or approved the studies, but they diverted the fees paid by the clinical study sponsors from the college to their accounts and established a site away from the

[22] Available at http://www.fda.gov/foi/nidpoe/n32l.htm.
[23] Available at http://www.timesunion.com/AspStories/story.asp?storyID=645743&TextPage=1.

college campus where they conducted the trials. *See* Proposal to Debar; Notice of Opportunity of Hearing Letter to Bruce I. Diamond from FDA (Nov. 26, 2002).[24]

In addition to violating the terms of their employment with the Medical College, Borison's and Diamond's misconduct extended to the manner in which the trials were conducted. Diamond, who is not a physician, forged Borison's name with Borison's knowledge on prescriptions in order to illegally dispense and prescribe medicine to study patients and on patient charts and other documents. Their employees stated that they felt pressure from Borison and Diamond to enroll patients in the trials, even if the patients were not qualified, to the point that they misled patients about the effects of the trial drug and did not obtain consent. *See* Steve Stecklow and Laura Johannes, Test Case: Drug Makers Relied on Clinical Researchers Who Now Await Trial – Two Professors Are Accused of Endangering Patients and Stealing $10 Million – "Checks and Balances" Failed, Wall Street J., Aug. 15, 1997, at A1. Further, Diamond and Borison together bribed an employee in order to obtain her cooperation and silence with regard to the attempted suicide of a study participant. As a result of this conduct, in October 1998, Borison pleaded guilty to 36 counts, including theft, making false statements, and racketeering. Diamond pleaded guilty in December 1997 to 53 counts, including theft, bribery, making false statements, and violation of the Georgia Controlled Substances Act.

While FDA's separate proposals to debar Borison and to debar Diamond mirror each other with respect to the factual bases for debarment, and acknowledge that Borison and Diamond worked collaboratively when establishing and operating their research facility, FDA debarred only Dr. Borison on September 30, 2003. *See* Richard L. Borison; Debarment Order, 68 Fed. Reg. 56,298 (Sept. 30, 2003).[25] Dr. Borison's permissive debarment is in addition to his disqualification, which FDA imposed by consent agreement on November 10, 1998. *See* FDA Disqualification List, available at http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm. FDA attempted to debar Diamond as well, but he was only disqualified by consent agreement on February 10, 1999. *See* Proposal to Debar; Notice of Opportunity of Hearing Letter to Bruce I. Diamond, Ph.D., from FDA (Nov. 26, 2002).[26] It is not clear from the documents available to Minority Staff why FDA actions resulted in treating differently two individuals who were involved in the same enterprise and convicted of many of the same felonies under State law for the same underlying conduct with respect to the development and approval and regulation of drugs.

5. The Gonsalves and Courtney Cases

The Gonsalves and Courtney cases involve similar fact patterns but resulted in different disciplinary treatment. Wallace Gonsalves, a physician, and Robert Courtney, a pharmacist, both diluted medications for patients. Both were convicted of felonies under Federal law relating to a drug product, thereby making them eligible for mandatory debarment, and are incarcerated. Only Courtney, however, has been debarred by FDA.

[24] Available at http://www.fda.gov/ohrms/dockets/dailys/02/Dec02/121902/00n-1531.pdf.
[25] Available at http://www.fda.gov/OHRMS/DOCKETS/98fr/03-24656.htm.
[26] Available at http://www.fda.gov/ohrms/dockets/dailys/02/Dec02/121902/00n-1531.pdf.

Robert Ray Courtney was a pharmacist in Kansas City, Missouri. Courtney dispensed medications to patients for a number of illnesses and conditions, including cancer. A pharmaceutical representative from Eli Lilly became suspicious that Courtney was selling more of Eli Lilly's chemotherapy drug, Gemzar, than he was buying from the representative. The representative mentioned his concern to an oncologist, who then decided to test one of Courtney's prescriptions at a laboratory. That test showed that the medication was diluted. *See* Robert Draper, The Toxic Pharmacist, N.Y. Times, June 8, 2003.[27]

The resulting criminal investigation revealed that over the course of approximately 11 years, Courtney diluted 98,000 prescriptions for 4,200 patients. Federal law enforcement tests showed that the dilution ranged from zero percent of the required dosage to 39 percent. Courtney adulterated a total of 72 drugs, including cancer and chemotherapy drugs, antibiotics, fertility drugs, drugs to prevent nausea and drugs to improve blood clotting. He also substituted generic drugs for prescription drugs, while charging for a prescription drug. Tragically, Courtney's fraud resulted in the deaths of 17 cancer patients. *Id*; *see also* Robert Cockburn, Death by Dilution, The American Prospect, Nov. 20, 2005.[28]

On February 26, 2002, Courtney pleaded guilty to eight counts of tampering with consumer products and six counts each of misbranding and adulterating drugs. Ten months later, on December 5, 2002, he was sentenced to 10 years in prison. Approximately 6 months later, on May 8, 2003, FDA issued a proposal to debar Courtney. *See* Proposal to Debar; Notice of Opportunity of Hearing Letter to Robert Ray Courtney from FDA (May 8, 2003).[29] The final debarment order was entered on October 20, 2003. *See* Robert Ray Courtney; Debarment Order, 68 Fed. Reg. 59,942 (Oct. 20, 2003).[30]

FDA's swift action in the Courtney case stands in contrast to its inaction in the Gonsalves case. Wallace Gonsalves was a physician practicing in Cranston, Rhode Island. As part of his practice, Gonsalves vaccinated immigrant patients. During his trial on charges of product tampering and drug adulteration, evidence showed that Gonsalves had diluted immigrant patients' vaccines for measles, mumps, and the varicella virus. *See* Press Release, United States Department of Justice, Cranston Doctor Found Guilty Accused of Diluting Vaccines, False Reports, and Tax Fraud, (March 17, 2003).[31] In fact, according to a spokeman for the United States Attorney, Gonsalves had a "two-tiered" level of care: "one for what he called his 'regular patients' and one for those he considered less deserving." *Id*. The extent of Gonsalves's fraud, and the harm to his patients, is startling. Gonsalves administered 673 patients with chickenpox vaccine when the supply was only 70 doses; from only 100 doses of the measles, mumps, and rubella (MMR) vaccine, 591 patients were vaccinated; and of 90 tetanus doses, 499 patients were vaccinated. *See United States v. Gonsalves*, 435 F.3d 64, 69 (1st Cir. 2006). In addition

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[27] Available at http://query.nytimes.com/gst/fullpage.html?res=9502E2DA1230F93BA35755C0A9659C8B63.
[28] Available at http://www.prospect.org/cs/articles?article=death_by_dilution.
[29] Available at http://www.fda.gov/ohrms/dockets/dailys/03/May03/052803/03n-0102-let0001-vol1.pdf.
[30] Available at http://www.fda.gov/OHRMS/DOCKETS/98fr/03-26385.htm.
[31] Available at http://www.usdoj.gov/tax/usaopress/2004/txdv04gonsalvesverdict.pdf.

to diluting the vaccines, Gonsalves directed his staff to take the vaccines for immigrants from "poorly marked water bottles stored for long periods in a refrigerator, the vaccine material itself being greatly diluted as well as aged." *Id*. Finally, Gonsalves falsified reports to the Department of Health and Human Services and Immigration and Naturalization Service (now, Immigration and Customs Enforcement) about the tests administered to his patients for HIV and syphilis. *See* Press Release, United States Department of Justice, Cranston Doctor Found Guilty Accused of Diluting Vaccines, False Reports, and Tax Fraud, (March 17, 2003).

On March 17, 2003, Gonsalves was found guilty by a jury of two counts of tampering with a consumer product, two counts of adulterating a drug, 23 counts of making materially false statements to Federal officials, two counts of tax evasion and two counts of making false statements on an income tax return. *See id.* Gonsalves was sentenced to 10 years in prison, and a Federal court of appeals upheld his conviction on January 20, 2006. To date, FDA has issued neither a notice of debarment nor a NIDPOE letter to Gonsalves.

FDA's failure to debar Gonsalves is, again, baffling. While Minority Staff did not find evidence that Gonsalves's fraud resulted in the death of a patient, his actions nonetheless jeopardized the health of his patients and the public health generally, through his failure to properly immunize his patients. Yet, as a matter of law, Gonsalves remains eligible to participate in clinical trials and receive investigational drugs. It is also difficult to determine from public documents FDA's rationale as to the reason debarment was imposed in the Courtney case but not in the Gonsalves case, even though the statutory requirements would seem to be satisfied.

6. The Hoffman-MacNay and Theodore-Rodgers Cases

Like the Gonsalves and Courtney cases, the cases of Allen J. Hoffman and Donald MacNay, and Thomas Ronald Theodore and Thomas M. Rodgers, have similar fact patterns but resulted in different outcomes. Theodore and Rodgers formed a business that sold products they claimed could treat AIDS and cancer. Hoffman and MacNay, too, were partners in a business that marketed a drug they claimed could treat cancer. All four individuals were found to have conned the public, including cancer patients, by making false claims about their products; all four men were convicted of crimes that made them eligible for debarment. Only Theodore and Rodgers have been debarred by FDA.

Theodore, a businessman from Atlanta who posed as a physician, started a company that distributed "LK-200," a drug that was created by spinning human blood cells in a centrifuge and skimming off the liquid on top, called "supernatant." A company, Private Biologicals Corporation (PBC), in Woburn, Massacusetts, manufactured the drug and shipped it to the Bahamas; Theodore then arranged for the drug to be shipped to pharmacists, physicians, and patients in the United States. *See* Thomas Ronald Theodore; Debarment Order, 68 Fed. Reg. 46197 (Aug. 5, 2003).[32] Evidence presented at trial showed that the drug was produced in "sub-standard

[32] Available at http://www.fda.gov/OHRMS/DOCKETS/98fr/03-19806.htm.

conditions that exposed the product to contamination." *United States v. Theodore*, 354 F.3d 1, 4 (1st Cir. 2003). The drug was never approved by FDA. According to prosecutors, Theodore conned investors and dying AIDS and cancer patients into investing more than $1 million in the drug. Rodgers was Chairman of the Board of Directors of PBC. *See id.* at 3.

In March 2001, a Federal jury convicted Theodore of nine counts of mail fraud, a felony under Federal law, and three counts of violating the Food, Drug and Cosmetic Act, and was sentenced to 121 months in prison and ordered to pay over $1 million in restitution to his defrauded investors. *See Theodore*, 354 F.3d at 5. On December 17, 2002, FDA sent Theodore a notice proposing permanent debarment. The final debarment order was issued on August 5, 2003. Rodgers of PBC pleaded guilty on May 4, 2000, to three, Federal misdemeanor charges, specifically, owning and operating an unregistered facility for the manufacture of drugs, shipping an unapproved drug in interstate commerce, and shipping an adulterated drug in interstate commerce. Just under 2 years later, on December 17, 2002, FDA sent Rodgers a proposal to debar him for a period of 5 years. Rodgers was debarred on July 28, 2005. *See* Thomas M. Rodgers, Jr.; Denial of Hearing; Debarment Order, 70 Fed. Reg. 43,699 (July 28, 2005).[33]

From 1996 through 1997, Hoffman and Dr. MacNay, an orthopedic surgeon, also distributed an unapproved drug that they claimed could treat HIV and cancer. The drug, which was distributed through a company called T-UP, was a 2-week treatment of intravenous aloe vera. Patients traveled from the United States to the Bahamas and Mexico to receive injections. Hoffman and MacNay charged approximately $12,000 for the 2-week treatment. The company also marketed bottled combinations of aloe vera for $75 per bottle and other unapproved drugs as helping to fight autoimmune diseases. *See* Michelle Meadows, Investigators' Reports: Maryland Man, Virginia Physician Sentenced for Illegally Marketing Aloe Vera 'Treatments', FDA Consumer, May-June 2002.[34]

Hoffman used mass mailings, radio commercials, video and audio tapes, telephone solicitations, and the Internet to market his product. One audiotape was titled, "There is Hope: You Do Not Have to Die!" *Id.* Over 3,000 individuals received Hoffman's and MacNay's aloe vera treatments. The T-UP company also shipped over 30,000 bottles of T-UP to customers. According to FDA agents, neither Hoffman nor MacNay informed their customers that the T-UP product had not been approved by FDA. In addition, Hoffman claimed the drug did not have side effects; however, he did not inform his patients that the drug contained cesium chloride, which can cause irregular heartbeat and reduce potassium levels. According to an FDA Office of Criminal Investigations agent, "There is no question that Hoffman took advantage of people by giving them false hope." *Id. See also* Press Release, United States Department of Justice, Indictments in "T-Up" Case (July 7, 1999).[35] Law enforcement officials learned about Hoffman's and MacNay's activities in 1997 after family members of a patient reported that a Texas man had died following a procedure performed by MacNay.

[33] Available at http://www.fda.gov/OHRMS/DOCKETS/98fr/05-14967.htm.
[34] Available at http://www.fda.gov/FDAC/departs/2002/302_irs.html.
[35] Available at http://healthfraud.org/tx/news/aloe.htm.

On July 7, 1999, Hoffman, MacNay, T-Up, Inc., and an associate, Odus M. Hennessee, were indicted in Federal court in Maryland on 20 counts of conspiracy to commit violations of Federal law relating to the sale, promotion, and distribution of an unapproved drug.[36] Hoffman pleaded guilty on September 21, 2001, to two counts of introducing an unapproved drug into interstate commerce and was sentenced in December 2001 to approximately 4 years in prison and ordered to pay $222,506 in restitution to the investors in his business whom he defrauded. Dr. MacNay pleaded guilty to fraud and conspiracy charges on March 29, 2000, and received a 2-year prison sentence. *See* Michelle Meadows, Investigators' Reports: Maryland Man, Virginia Physician Sentenced for Illegally Marketing Aloe Vera 'Treatments', FDA Consumer, May-June 2002.[37] Hoffman and MacNay were never debarred by FDA and, unfortunately, it is now too late to do so, as 5 years has passed since the date of their convictions.

Again, like the cases discussed previously, Hoffman and MacNay were convicted of felonies relating to the regulation of a drug product. FDA, therefore, was required to initiate mandatory debarment proceedings. Considering that mandatory debarment was imposed in a similar case, the Theodore case, and that the requirements for mandatory debarment were clearly met, there seems from available information to be no conceivable reason that debarment was not imposed here other than an oversight on the part of FDA.

7. The Fiddes Case

Yet another example of FDA's inconsistent treatment of clinical investigators is the debarment of Dr. Robert A. Fiddes. Dr. Fiddes was initially the subject of an FDA NIDPOE letter on September 12, 1997 because FDA found that Dr. Fiddes repeatedly and deliberately violated Federal regulations by submitting false information to sponsors in a clinical trial. Eighteen days after FDA sent the NIDPOE letter, Dr. Fiddes pleaded guilty in Federal court to one count of conspiring to make false statements to a government agency. Even though the FDA had initiated disqualification proceedings, FDA sent a notice to Dr. Fiddes proposing to debar him because he was convicted of a felony for making false statements. Dr. Fiddes was debarred on November 6, 2002. *See* Robert A. Fiddes; Debarment Order, 67 Fed. Reg. 67,628 (Nov. 6, 2002).[38] Again, from the documents available to Minority Staff, it is difficult to understand given that Dr. Fiddes was debarred, why Dr. Holland was not debarred or, at least, disqualified for providing false information in a clinical trial.

[36] The counts included one count of conspiring to introduce an unapproved new drug into interstate commerce and to commit wire and mail fraud; five counts of introducing an unapproved new drug into interstate commerce; four counts of mail fraud; and ten counts of wire fraud.
[37] Available at http://www.fda.gov/FDAC/departs/2002/302_irs.html.
[38] Available at http://www.fda.gov/ora/compliance_ref/debar/dbarfedreg/fiddes2002.pdf.

8. Copanos Cases

The FDA investigation of John D. Copanos and Consolidated Pharmaceutical Group (CPG) is a stunning example of both FDA's inconsistent treatment of individuals subject to debarment and the ineffectiveness of debarment enforcement, all within the same case.

In 1996, FDA permanently debarred John D. Copanos, the owner and President of Copanos and Sons, Inc., and Kanasco, Ltd., when Copanos pleaded guilty to one count of distributing misbranded drugs with intent to mislead. *See* John D. Copanos; Denial of Hearing; Final Debarment Order, 61 Fed. Reg. 9,711 (March 11, 1996).[39] The drug was considered misbranded because it did not contain adequate directions for its use and did not disclose that it contained phenylalanine, a component in aspartame. *See id*. One year later, in 1997, James H. Coleman, the President of CPG, provided affidavits to the court stating that Copanos was no longer associated with the company. *See* FDA, "The Enforcement Story, Fiscal Year 2004," at 6.[40]

Just 3 years later, FDA's Baltimore, Maryland, field office initiated a second investigation of Copanos when it received information that he continued to be involved in CPG's operations. *See id.* Federal investigators substantiated that Copanos was, in fact, a substantial participant in the company's operations. Based on this investigation, Coleman, the President of CPG, was convicted on March 27, 2001, of violating 18 U.S.C. § 1001 for making false statements. Copanos and his son, John S. Copanos, were also indicted in October 2001 for conspiracy and making false statements under 18 U.S.C. §§ 371 and 1001, respectively. Ultimately, John D. Copanos was convicted of conspiracy in 2003; charges against his son were dropped.

At the least, FDA had a case against Coleman for permissive debarment. In his capacity as President of a pharmaceutical company, he assured a Federal court while under oath that Copanos, who had been convicted of introducing a misbranded drug into commerce, was no longer involved with the company. He later admitted those statements were false. Coleman's conviction demonstrates a disregard for his responsibility as President of a drug company to assure the safety of the drug supply, and of his duty to speak truthfully when under oath. Yet, FDA has not debarred him.

Copanos's continued participation in the drug industry raises additional, troubling questions about FDA's approach to enforcement, in particular, what follow-up or monitoring FDA conducts of individuals once they are debarred.

[39] Available at http://www.fda.gov/ora/compliance_ref/debar/dbarfedreg/copa396.txt.
[40] Available at http://www.fda.gov/ora/about/enf_story2004_archive/ch6/default.pdf.

D. FDA Has Failed to Bring Timely Debarments, Raising Risks of Criminals Continuing Their Participation in Clinical Trials or Other Drug Company Activities.

Not only does FDA fail to pursue debarment in cases where a basis for debarment seems to exist, FDA often fails to pursue debarment in a timely manner.

As set forth in the March 22, 2007, letter to Inspector General Levinson, a review by Minority Committee Staff of the 21 FDA debarment actions since 2000 showed that, on average, 38 months elapsed between the date an individual was convicted of a crime relating to the development or approval of a drug product and the FDA's notice of debarment.

In one case, FDA's failure to send a timely notice of debarment to the correct address resulted in the notice being rescinded. On October 22, 1997, Delfina Hernandez pleaded guilty to a felony under Federal law for making false statements to FDA, as Hernandez had falsified data and information in a clinical study. Almost 5 years after the date of her conviction, FDA issued a notice of debarment to Hernandez; however, the notice was sent to the wrong address and thus failed to meet the requirement under 21 U.S.C. § 335a(l)(2) that a notice of debarment be sent within 5 years of the date of conviction. *See* Letter from Delfina Hernandez to FDA (Nov. 25, 2002).[41] This error resulted in the notice being rescinded. *See* Letter to Delfina Hernandez from FDA (March 18, 2003).[42] In another instance, the information on FDA's debarment list shows that FDA failed to meet the 5-year deadline for sending a notice of debarment, yet the notice was not rescinded. Again, these lapses are significant, because Federal law does not prevent an individual convicted of a crime relating to the development or approval of a new drug from continuing to receive investigational drugs or providing services to another individual or corporation with a pending drug application during the period preceding debarment.

In another case, FDA may have debarred an individual they had no authority to debar. In the case of Dr. Mohammed Uddin, FDA did not publish a notice of proposed debarment until January 19, 1999, which was over 5 years after his conviction on November 19, 1993. *See* Mohammad Uddin; Proposal to Debar; Opportunity for Hearing Letter from FDA, 64 Fed. Reg. 1809 (Jan. 12, 1999). Moreover, it took FDA nearly 2 years to effectuate the debarment, even though Dr. Uddin waived his opportunity for a hearing; Dr. Uddin was not debarred until September 29, 2000 – almost 7 years after his conviction. *See* Mohammad Uddin; Debarment Order, 65 Fed. Reg. 58,557 (Sept. 29, 2000).[43]

FDA's tardiness in pursuing disciplinary action against the investigator who had enrolled the largest number of subjects in the Ketek trial, Dr. Anne Kirkman-Campbell, illustrates this point. Dr. Anne Kirkman-Campbell was a physician in Gadsden, Alabama. During the Subcommittee's investigation, Committee Staff learned of several

[41] Available at http://www.fda.gov/OHRMS/DOCKETS/dailys/02/Nov02/112502/00n-1528-let0002-vol1.pdf.
[42] Available at http://www.fda.gov/ohrms/DOCKETS/dailys/03/Mar03/032403/800582a9.pdf.
[43] Available at http://www.fda.gov/ora/compliance_ref/debar/dbarfedreg/marc-dbr00.pdf.

problems that had occurred during the trial at Dr. Kirkman-Campbell's site, in particular, that the Kirkman-Campbell site had enrolled over 400 patients, a number that some witnesses considered unusual given the population of Gadsden; under-reporting of adverse events; and discrepancies in the informed consent forms and documentation in medical charts.

Following an inspection of Dr. Kirkman-Campbell's offices by FDA's Division of Scientific Investigations (DSI) on October 15-24, 2002, several problems were identified including multiple violations of Good Clinical Practices (GCPs), including enrollment of patients in Study 3014 who should have been excluded; documentation showing that certain patients received a course of Ketek when those patients stated that they did not receive the drug; and no reports of adverse reactions for the first 100 patients who were enrolled at Dr. Kirkman-Campbell's site. As a result, the OCI initiated an investigation of Dr. Kirkman-Campbell.[44] Ultimately, Dr. Kirkman-Campbell was indicted on 21 Federal felony charges for her conduct during the Ketek drug trial on August 23, 2003. Two months later, on October 23, 2003, Dr. Kirkman-Campbell pleaded guilty to one count of Federal mail fraud and was sentenced to 57 months in prison on March 24, 2004. *See* Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) Letter from FDA to Anne Kirkman Campbell, M.D. (May 18, 2006).[45]

Although Dr. Kirkman-Campbell was clearly eligible for mandatory debarment because she had pleaded guilty to a felony under Federal law for her conduct relating to the Ketek safety trial, Minority Committee Staff discovered that FDA did not initiate debarment proceedings until February 28, 2007, almost 3 years after Dr. Kirkman-Campbell was incarcerated.[46] So, even though Dr. Kirkman-Campbell is in prison, as a matter of law, she can continue to provide services to a drug company that has a pending or approved drug application before the FDA, including, but not limited, to work in clinical trials. In addition, she remains eligible to receive investigational drug products until the date of debarment. *See* Proposal to Debar; Notice of Opportunity of Hearing Letter to Maria Anne Kirkman-Campbell, M.D., from FDA (May 16, 2007).[47]

Dr. Borison's case, discussed in Section III-C, is another example of the delay between a clinical investigator's date of conviction and the date on which FDA finally imposes debarment. In Dr. Borison's case, almost 5 years had passed since his conviction before FDA ensured with his debarment that he was not able to participate in trials or receive investigational drugs.

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[44] Unlike the Division of Scientific Investigation, the Office of Criminal Investigations is not part of CDER. Instead, the Office of Criminal Investigations is essentially autonomous but is organizationally part of FDA's Office of Regulatory Affairs.

[45] Available at http://www.fda.gov/foi/nidpoe/n41l.pdf.

[46] FDA did issue a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain Letters (NIDPOE) letter to Dr. Kirkman-Campbell on May 18, 2006 — a full two years after her sentencing date — but those proceedings had not concluded. *See* fn. 38. Why FDA pursued a disqualification of a convicted felon instead of debarment is yet another mystery.

[47] Available at http://www.fda.gov/ohrms/dockets/DOCKETS/06n0238/06n-0238-let0003-vol1.pdf. According to FDA's dockets, as of January 8, 2008, FDA and Dr. Kirkman-Campbell had exchanged seven letters related to FDA's proposed debarment.

The delay between the date of conviction and the date on which FDA pursues debarment is particularly striking when contrasted to the speed with which the Federal Communications Commission (FCC) pursues debarment proceedings. The FCC has both suspension and debarment authority over individuals who have been convicted or found civilly liable for acts arising from their participation in the Schools and Libraries Program. Upon learning that there is "cause" for suspension or debarment, that is, "conviction of or civil judgment for attempt or commission of criminal fraud, theft, embezzlement, forgery . . . and other fraud or criminal offense arising out of activities associated with or related to the schools and libraries support mechanism," FCC suspends that individual from all activities related to the program and issues a Public Notice of Suspension and Proposed Debarment. *See* FCC Suspension and Debarment Rules, 47 C.F.R. §§ 54.521 and 54.8 (2004). The individual then has 30 days to contest the debarment.

To date, since the FCC published its debarment regulations in 2003, 13 individuals have been debarred. The period between the date the notice of debarment was issued by the FCC and debarment imposed ranged from 3 months to 25 months, with an average period of just over 8 months between notice and debarment. This period stands in sharp contrast to the 38 months, on average, it takes FDA just to notice debarment proceedings after an individual is convicted of a crime relating to a drug product.

E. FDA Has Failed to Debar Individuals Convicted of Crimes Relating to Misconduct Before Other Federal Agencies.

Under the Generic Drug Enforcement Act, FDA has authority to debar individuals who, while not convicted of crimes relating to a drug product, are nonetheless subject to debarment because their crime involves bribery, fraud, perjury, extortion or similar crimes and the Secretary finds there is reason to believe the individual may violate requirements relating to drug products. However, Minority Staff's review of FDA debarments has revealed that FDA has failed to invoke this authority, even when the individual in question has defrauded another United States agency or department.

Dr. Suvarna Shah was a subject of a United States Department of Justice investigation named "Operation Free Shot." Dr. Shah had participated in the Vaccines for Children program. Under this program, in exchange for receiving free vaccines, Dr. Shah agreed not to bill Medicaid or any other third party payor for the cost of the vaccines. However, Dr. Shah billed over $350,000 in charges to Medicaid and other insurance programs for childhood vaccines she had received free-of-charge. In the end, Dr. Shah pleaded guilty in May 2004 to one count of health care fraud and one count of tax evasion. *See* Press Release, United States Department of Justice, Doctor Pleads Guilty to Federal Health Care, Tax Fraud Charges (May 20, 2004).[48]

As evidenced by the charges against her, Dr. Shah's misconduct clearly involves fraud and involved another department of the United States Government, the Department

[48] Available at http://www.usdoj.gov/usao/ct/Press2004/20040520-2.html.

of Health and Human Services. To debar her, FDA must find that Shah "demonstrated a pattern of conduct sufficient to find there is reason to believe [she] may violate requirements relating to drug products." For a period of 5 years, Shah had participated in a scheme whereby she fraudulently billed the Federal government and the State of Connecticut for over $350,000 in fees, but FDA has not initiated debarment proceedings against her. Shah, therefore, remains eligible to receive investigational products and provide services to companies submitting drug applications to FDA.

Similarly, FDA has not initiated disciplinary proceedings against Dr. Vimlesh Ahmad, a physician who "up-coded" bills for the office visits of Medicaid patients. In addition, Dr. Ahmad had engaged in conduct that had serious consequences for patient health, including accepting payment from patients addicted to pain medications in exchange for prescriptions, selling sample medications left at her office by pharmaceutical representatives, and falsifying a chart when a patient died of acute opiate poisoning after being over-medicated. As a result of this conduct, in 2004, Dr. Ahmad was convicted of one count of health care fraud and sentenced to 12 months in prison and distributed pharmaceutical drugs without a physical exam, patient history, or an appropriate treatment plan. She also surrendered her State medical license and Drug Enforcement Agency (DEA) number. *See* FDA, Office of Criminal Investigations, "The Enforcement Story, Fiscal Year 2004," at 22.[49]

Over 3 years have passed since Dr. Ahmad's conviction. To date, FDA has not initiated any disciplinary proceedings against her. Like Dr. Shah, nothing prevents Dr. Ahmad from providing services to a company with a pending drug application or participating in a clinical trial. Moreover, as in other cases, FDA's failure to take action against Dr. Ahmad raises questions about the consistency with which FDA administers its debarment authority. In 1994, FDA permanently debarred Patrick T. Ryan after he was convicted in 1993 of a felony under Federal law for knowingly selling, purchasing, and trading drug samples. As the FDA stated in its notice to permanently debar Ryan, this crime relates to the regulation of a drug product, thereby making Ryan eligible for debarment. FDA's treatment of Ryan directly contrasts with its failure to take any action against Dr. Ahmad. Both individuals illegally sold or traded drug samples, yet only Ryan has been debarred by FDA.

IV. CONCLUSION

Congress granted debarment authority to FDA to serve a remedial purpose: to restore or maintain consumer confidence and to protect the integrity of the FDA regulatory process by excluding bad actors from the drug industry. Unfortunately, the Minority Committee Staff found that the FDA's record on debarments reveals serious deficiencies in meeting the remedial purpose of the GDEA.

FDA is hampered in two ways. First, FDA lacks adequate authority. Under the statute, the agency cannot debar companies other than those that submit generic drug applications. The FDA also lacks authority to debar companies for post-approval

[49] Available at http://www.fda.gov/ora/about/enf_story2004_archive/ch6/default.pdf.

criminal conduct. Second, FDA lacks focus in its debarment actions. A review of some cases involving debarred and non-debarred individuals convicted of FDA-related crimes demonstrates FDA's uneven application of its debarment authority. FDA's debarment record also shows unacceptable delays in starting the debarment process. It is doubtful that this is simply a matter of resources. As the debarment record of the FCC shows, other agencies have been able to start and complete debarments promptly. Instead, the GDEA's 5-year window to start the debarment process may be giving the FDA the perverse incentive not to move quickly on debarments.

The examples discussed in this report serve as case studies of FDA debarment actions or inactions, but they raise larger questions about the manner in which FDA carries out its authority under the GDEA. In cases where the factual predicate is similar, like that of Dr. Borison and Dr. Diamond, FDA took action in one case but apparently was unable to do so with the other. FDA debarments have serious consequences for the subjects of the debarment, but they also impact the well-being of individuals who participate in clinical trials or who are ultimately prescribed the drug products regulated by FDA. It is therefore essential that FDA debarments be administered promptly and consistently when circumstances require them, so that the safety of our drug supply and our health is ensured.

To address the disparity with regard to the corporations eligible for debarment, Congress should consider extending debarment provisions enacted in the Generic Drug Enforcement Act to name-brand companies, animal drug companies, biologic companies and medical device companies. In addition, Congress should consider whether a company's misconduct that occurs after a drug product is approved should be a basis for debarment. Congress should also consider changes in the statute that would incentivize the FDA to start and complete debarments more quickly and efficiently.

Internally, FDA should also review its procedures for determining when an individual or corporation is subject to debarment proceedings. The results of this review should be shared with the public so as to increase its confidence that FDA is administering its authority consistently and in a timely manner.

ATTACHMENT A

FDA Mandatory and Permissive Debarment
21 U.S.C. § 335a

	Mandatory Debarment (Corporations, Partnerships, Associations)	**Mandatory Debarment (Individuals)**	**Permissive Debarment (Corporations, Partnerships, Associations)**	**Permissive Debarment (Individuals)**
Subject	Corporations, partnerships, associations	Individuals	Corporations, partnerships, associations	Individuals
Predicate Acts	Secretary finds that corporation has been convicted *after May 13, 1992* of a *felony under Federal law* for *conduct relating to the development or approval or any abbreviated drug application.*	Secretary finds that individual has been convicted of a felony under federal law for conduct (1) relating to the *development of approval of any drug product*, or (2)otherwise relating to the *regulation of any drug product under 21 U.S.C. Chapter 9.*	Secretary finds that corporation has been convicted for conduct that: (1) relates to drug development/approval of any abbreviated drug application and is a felony under Federal law (if person convicted before May 13, 1992), a misdemeanor under Federal law, or felony under state law, or (2) of conspiracy to commit or aiding an abetting the criminal offense described in (1) or conspiracy to commit or aiding and abetting a felony relating to the development or approval of a drug application for which an individual was convicted	There are four categories of predicate acts that can lead to permissive debarment. (1) The Secretary finds that an individual has been convicted of a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval of a drug product or conspiracy to commit or aiding an abetting a felony under Federal law for conduct relating to the development or approval or any abbreviated drug application, IF the Secretary finds that the conduct which served as the basis for conviction *undermines the process for the regulation of drugs.* (2) The Secretary finds that the person has been convicted of a felony *not*

	Mandatory Debarment (Corporations, Partnerships, Associations)	Mandatory Debarment (Individuals)	Permissive Debarment (Corporations, Partnerships, Associations)	Permissive Debarment (Individuals)
			after May 13, 1992, IF the Secretary finds that the conduct which served as the basis for conviction *undermines the process for the regulation of drugs.*	relating to the development or approval of a drug product and which involves bribery, fraud, perjury, making false statements, racketeering, blackmail, extortion, and similar crimes or a conspiracy to commit such felony IF the Secretary finds, on the basis of the individual's conviction and other information, that the individual has demonstrated a *pattern of conduct* sufficient to find *there is reason to believe the individual may violate requirements relating to drug products*. (3) The Secretary finds an individual has *materially participated* in acts that were the basis of a conviction of a felony under Federal law relating to the approval of drug products or for offenses described in (1) and (2) above, IF the Secretary finds that the individual demonstrated a *pattern of conduct* sufficient to find *there is reason to believe the individual may violate requirements relating to drug products*. (4) Any *high managerial agent* whom the Secretary finds had worked for a person during the period in which that person had committed acts for which a felony conviction was obtained and the

	Mandatory Debarment (Corporations, Partnerships, Associations)	Mandatory Debarment (Individuals)	Permissive Debarment (Corporations, Partnerships, Associations)	Permissive Debarment (Individuals)
				agent had knowledge of the actions, knew the actions violated law, and did not report the conduct or failed to take other appropriate action, IF the Secretary finds that the *conduct serving as the basis of conviction undermines the process for the regulation of drugs.*
Process for Taking Disciplinary Action	Mandatory. The Secretary must debar the corporation from *submitting or assisting in the submission of an application* if he finds that the predicate act took place.	Mandatory. The Secretary must debar the individual from providing services *in any capacity* to an individual/corporation that has an approved or pending drug product application.	Permissive. Secretary may initiate a permissive debarment on his own initiative or in response to a petition.	Permissive. Secretary may initiate a permissive debarment on his own initiative or in response to a petition.

	Disqualification	Mandatory Debarment (Corporations, Partnerships, Associations)	Mandatory Debarment (Individuals)	Permissive Debarment (Corporations, Partnerships, Associations)	Permissive Debarment (Individuals)
Disciplinary Action Taken	If Commissioner determines that predicate acts took place, Commissioner notifies investigator and sponsor of any investigations in which sponsor participated *that the investigator is not entitled to receive investigational drugs.*	Mandatory debarment from submitting or *assisting in the submission of an abbreviated drug application.* The Secretary shall not accept or review any application submitted by or with the assistance of the subject corporation during the debarment period.	Mandatory debarment from providing services *in any capacity* to an individual/corporation that has an approved or pending drug product application. The Secretary shall not accept or review an abbreviated drug application from a subject individual during the period of debarment.	Secretary may debar a corporation from *submitting or assisting in the submission of any abbreviated drug application.* The Secretary shall not accept or review any application submitted by or with the assistance of the subject corporation during the debarment period.	Secretary may debar any individual from *providing services in any capacity to a person that has an approved or pending drug product application.* The Secretary shall not accept or review an abbreviated drug application from a subject individual during the period of debarment.
Period of Disqualification/ Debarment	At discretion of Commissioner. See below.	Not less than one year or more than 10 years. If a subsequent, mandatory debarment occurs within 10 years of a preceding mandatory debarment, debarment is permanent.	Permanent.	Not more than five years. The Secretary shall determine if debarment periods for multiple offenses will run concurrently or consecutively.	Not more than five years. The Secretary shall determine if debarment periods for multiple offenses will run concurrently or consecutively.
Reinstatement Possible	21 CFR § 312.70 states that investigator may be reinstated as eligible to receive investigational drugs "when the	Yes. Corporation subject to mandatory debarment may apply to Secretary for termination of	No. If the conviction serving as the basis of the debarment is *reversed*,	Yes. Corporation subject to permissive debarment may apply to Secretary for termination of	Yes. Individual subject to permissive debarment may apply to Secretary for termination of debarment.

	Disqualification	Mandatory Debarment (Corporations, Partnerships, Associations)	Mandatory Debarment (Individuals)	Permissive Debarment (Corporations, Partnerships, Associations)	Permissive Debarment (Individuals)
	Commissioner determines that investigator has presented *adequate assurances* that he will comply with Parts 312, 50, and 56.	debarment. If the conviction serving as the basis of the debarment is *reversed*, Secretary shall withdraw order of debarment. The corporation may also apply for a "special termination" of debarment. The Secretary may immediately terminate the debarment or limit it to a period of less than one year if he finds that the felony conviction involved an offense not authorized or requested by the corporation; the individuals involved in the offense have all been removed from employment involving the development of drugs; the corporation fully cooperated will all investigations and promptly disclosed wrongdoing; and the	Secretary shall withdraw order of debarment. The individual may also apply for a "special termination" of debarment. To be granted, the Secretary must determine after an informal hearing that the individual has provided *substantial assistance to the investigations or prosecutions of subject offenses or any matter under FDA jurisdiction*	debarment. If the conviction serving as the basis of the debarment is *reversed*, Secretary shall withdraw order of debarment. Special termination of debarment is not an option for permissive debarments.	If the conviction serving as the basis of the debarment is *reversed*, Secretary shall withdraw order of debarment. Special termination of debarment is not an option for permissive debarments.

	Disqualification	Mandatory Debarment (Corporations, Partnerships, Associations)	Mandatory Debarment (Individuals)	Permissive Debarment (Corporations, Partnerships, Associations)	Permissive Debarment (Individuals)
		person acted to mitigate impact to public.			

ATTACHMENT B

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

March 22, 2007

The Honorable Daniel R. Levinson
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Room 5541, Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Inspector General Levinson:

The Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of Food and Drug Administration ("FDA") efforts to assure the safety of the drug supply. As part of this inquiry into FDA's handling of New Drug Applications and post-market review of adverse drug side effects, we are examining a case study involving the antibiotic telithromycin, or "Ketek."

One troubling aspect of this Ketek case study involves misconduct by a clinical investigator, Dr. Anne Kirkman-Campbell. The Kirkman-Campbell case raises concerns about deficiencies in FDA enforcement against clinical investigators engaged in serious misconduct. In particular, we are concerned about information showing that FDA has not made use of debarment and disqualification proceedings under 21 U.S.C. § 335a or 21 C.F.R. § 312.70, respectively, in a timely and consistent manner.

On August 29, 2003, Dr. Anne Kirkman-Campbell was indicted by a federal grand jury on 21 charges relating to her participation in a clinical trial of the investigational drug Ketek, performed for Aventis Pharmaceuticals, Inc. Ultimately, Dr. Kirkman-Campbell pleaded guilty to one count of Federal mail fraud on October 23, 2003 and was sentenced to 57 months in prison on March 24, 2004. Although Dr. Kirkman-Campbell pleaded guilty over three years ago to a felony under Federal law relating to her conduct in the development or approval of a drug product, to date, she has not been debarred pursuant to 21 U.S.C. § 335a(2). If FDA had permanently debarred Dr. Kirkman-Campbell under 21 U.S.C. § 335a(2), as the statute clearly provides due to

her conviction, Dr. Kirkman-Campbell could not provide services in any capacity to a person that has a pending or approved drug application before the FDA, including, but not limited, to work in clinical trials. Moreover, Dr. Kirkman-Campbell has not been disqualified, a sanction that would also prevent her from participating in clinical trials. Two years passed after Dr. Kirkman-Campbell's sentencing date before FDA issued a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain Letters ("NIDPOE") letter to her on May 18, 2006. Because Dr. Kirkman Campbell has been neither debarred nor disqualified, as a matter of law, she is still eligible to receive investigational drugs even though she is currently incarcerated in a Federal institution.

The FDA's approach with Dr. Kirkman-Campbell stands in contrast to FDA's disciplinary action against Dr. Robert A. Fiddes. FDA sent a NIDPOE letter to Dr. Fiddes on September 12, 1997 because it found that Dr. Fiddes repeatedly and deliberately violated Federal regulations by submitting false information to sponsors in a clinical trial. Eighteen days after sending the NIDPOE letter, Dr. Fiddes pleaded guilty in Federal court to one count of conspiring to make false statements to a government agency. Even though the FDA had initiated disqualification proceedings against Dr. Fiddes on September 12, 1997, FDA sent a notice to Dr. Fiddes proposing to debar him because he was convicted of a felony for making false statements. Dr. Fiddes was debarred on November 6, 2002.

In addition to the apparently inconsistent treatment of Dr. Kirkman-Campbell and Dr. Fiddes, we are also concerned about whether FDA has taken timely action to either debar or disqualify clinical investigators under 21 U.S.C. § 335a or 21 C.F.R. § 312.70, respectively. In either debarment or disqualification, the investigator cannot be sanctioned without a costly and time consuming hearing that resembles a full trial with direct and cross examinations of witnesses. Specifically, a review by Minority Committee staff of the 21 FDA debarment actions since 2000 showed that, on average, 38 months elapsed between the date an individual was convicted of a crime relating to the development or approval of a drug product and the FDA's notice of debarment. In one instance, FDA sent a notice of debarment to the wrong individual, and thus failed to meet the requirement under 21 U.S.C. § 335a(l)(2) that a notice of debarment be sent within five years of the date of conviction. This error resulted in the notice being rescinded. *See* (Attached Letter/Chart). In another instance, the information on FDA's debarment list shows that FDA failed to meet the five-year deadline for sending a notice of debarment, yet the notice was not rescinded. These lapses are significant, because Federal law does not prevent an individual convicted of a crime relating to the development or approval of a new drug from continuing to receive investigational drugs or providing services to another individual or corporation with a pending drug application during the period preceding debarment.

Similar timeliness problems exist with respect to FDA's disqualification actions against clinical investigators. A review of 12 clinical investigators who received NIDPOE letters and who were subsequently disqualified revealed that an average of 2 years and 181 days elapsed between the date of the NIDPOE letter and the date of disqualification. In one instance, 6 years and 113 days elapsed from the date of the

NIDPOE letter to the date of disqualification. Even in the high-profile case of Dr. James Wilson, there was considerable delay. Dr. Wilson was the principal investigator of a controversial gene therapy experiment at the University of Pennsylvania which led to the death of a teenage participant in September 1999. Three HHS agencies, including FDA, alleged he made false statements and claims between July 1998 and September 1999. FDA sent a NIDPOE letter to Dr. Wilson in November 2000, but a restriction agreement was not finalized until February 2005.

Again, during the period between the date of the NIDPOE letter and the date of disqualification, the clinical investigator can continue to receive investigational drugs and, therefore, may have every incentive to delay the process. As was noted nearly 20 years ago in an article by Dr. Martin F. Shapiro, Chief, Division of Internal Medicine and Health Services Research at University of California Los Angeles, and Robert P. Charrow, former Deputy General Counsel of HHS, "[t]his delay often attenuates the deterrent effect of any disciplinary measure and minimizes the sponsoring drug manufacturers' economic risks, since they have ample opportunity to ensure that any research is completed before the effective date of disqualification."

Based on available information, the Minority Committee staff found a case where FDA failed to take sufficient action to disqualify or restrict a clinical investigator whom the agency had found to be submitting false information. In the case of Dr. Leonard Caputo, FDA determined that he submitted false information to FDA or the drug sponsor in required reports, yet no NIDPOE letter was issued. A drug sponsor complaint, asserting that Dr. Caputo falsified data, initiated a FDA inspection in August 2000. The FDA inspection identified significant deviations from Good Clinical Practice regulations including, but not limited to, the alteration of records to support the inclusion of ineligible subjects. FDA issued a warning letter asking Dr. Caputo to voluntarily sign a restricted investigator agreement, which he declined to do. To date, FDA has not issued a NIDPOE letter, and Dr. Caputo does not appear on any restricted investigators list.

The Minority Committee staff's review also raised questions about the accuracy and reliability of FDA records on the disposition of clinical investigator disqualification cases. For example, according to information on the FDA disqualification list, "restrictions" were placed on Dr. Arthur Riba on January 12, 2004; however, Minority Committee staff contacted Dr. Riba's counsel and learned that, in fact, no restrictions were placed on Dr. Riba's ability to participate in clinical trials. FDA's disqualification case against Dr. Riba went to trial before an administrative law judge and it was determined that Dr. Riba not be disciplined. Nevertheless, FDA public records show that disciplinary action was taken, when in fact there was none.

Not only are disciplinary proceedings delayed, and the subjects of those proceedings subject to inconsistent treatment, it appears that different Centers within the FDA are more active than others in pursuing disciplinary actions against clinical investigators. According to a June 2000 report by the Department of Health and Human Services, Office of Inspector General ("OIG"), entitled "FDA Oversight of Clinical Investigators" that Minority Committee Staff has reviewed during this investigation, of

the 189 official, FDA actions against clinical investigators from fiscal years 1994 to 1999, the vast majority, 107 official actions, were initiated by the Center for Devices and Radiological Health. Of the remaining actions, 58 were initiated by the Center for Drug Evaluation and Research and 24 by the Center for Biologics Evaluation and Research.

In addition, the report addresses other problems with FDA disciplinary action. In particular, the OIG characterized the FDA's oversight of clinical investigators as "limited" and "problematic" and found that FDA staff received little training or guidance with respect to selecting clinical investigators for inspection or determining when "repeated or deliberate" violations of clinical trial regulations have occurred. To improve FDA's oversight program, the OIG recommended that FDA define goals for its bioresearch monitoring program and develop internal guidance "on the severity and number of violations needed to justify beginning disqualification proceedings." In a brief submitted by the FDA in a December 2000 disqualification proceeding, the FDA argues that the Commissioner interpreted "repeated" as meaning "more than one violation." On its face, this definition is problematic because inadvertent violations of clinical regulations occur in all clinical trials given the thousands of data points usually involved, thus potentially subjecting virtually every clinical investigator to disqualification proceedings. Further, although the OIG report was issued almost seven years ago, the Minority Committee staff's preliminary review of FDA's oversight of clinical investigators raises a question about whether FDA has fully implemented the OIG's recommendations in the June 2000 report.

Given our concerns, we respectfully request that the Department of Health and Human Services Office of the Inspector General examine the following issues related to the FDA's oversight and discipline of clinical investigators:

1. Has the FDA implemented the recommendations from the OIG's June 2000 report? In particular:

    a. Has the FDA defined goals for the bioresearch monitoring program and developed criteria to determine whether the program is achieving those goals? If so, please examine whether the bioresearch monitoring program is effective in identifying clinical investigators whose practices or conduct may have compromised the quality and integrity of clinical data or the safety of the clinical trial participants.

    b. Has the FDA implemented guidance as to the definition of "repeated or deliberate" violations of the FDA clinical trial regulations? If so, please examine how the guidance has been implemented and whether the definition is workable and has been applied consistently.

2. Why are there delays with either FDA's initiating disciplinary proceedings against a clinical investigator who has engaged in

misconduct or imposing punishment after such proceedings are initiated? In particular:

a. What are the reasons for delay between a clinical investigator's date of conviction and the date of debarment pursuant to 21 U.S.C. § 335a? We ask that you examine the FDA's decisionmaking with respect to clinical investigators who were convicted of crimes relating to their conduct in a clinical trial but who were not subject to FDA debarment proceedings.

b. What are the reasons for delay between the date FDA initiated disqualification proceedings pursuant to 21 C.F.R. § 312.70 and the date of the investigator's disqualification? We ask that you examine whether FDA prioritizes the order in which it pursues disqualification proceedings against clinical investigators and whether FDA has failed to disqualify such investigators in some cases.

c. Has the FDA taken any action or can FDA take any action against a clinical investigator that would prevent that investigator from receiving investigational drugs during the period following his or her conviction of crimes relating to conduct in a clinical trial and preceding the date of debarment or disqualification?

Thank you for your consideration of this request. If you have any questions, please do not hesitate to contact Alan Slobodin or Karen Christian of the Minority Committee Staff at (202) 225-3641.

Sincerely,

Joe Barton
Ranking Member
Committee on Energy
and Commerce

Ed Whitfield
Ranking Member
Subcommittee on Oversight
and Investigations

Attachments

cc: The Honorable John D. Dingell, Chairman
The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable Andrew von Eschenbach, M.D., Commissioner
Food and Drug Administration

ATTACHMENT C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP 21 2007

The Honorable Joe Barton
Ranking Member, Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20510

Dear Mr. Barton:

I am writing in response to your March 22, 2007, letter requesting that my office examine issues related to the Food and Drug Administration's (FDA) oversight and discipline of clinical investigators. Specifically, you requested that the Office of Inspector General (OIG) examine whether FDA implemented recommendations from OIG's June 2000 report, "FDA Oversight of Clinical Investigators," and determine the reasons for delay with FDA either initiating disciplinary proceedings against clinical investigators who have engaged in misconduct or imposing punishment after such proceedings are initiated.

In particular, you asked whether FDA has defined goals for the bioresearch-monitoring program and developed criteria to determine whether the program is achieving those goals. As a result of our 2000 report, FDA created the Bioresearch Monitoring Steering Committee in 2004. The Committee is responsible for: (1) reviewing FDA's bioresearch-monitoring processes to ensure the quality and integrity of data and information submitted in support of investigational and marketing clearance applications or submissions, (2) ensuring that human subjects taking part in investigations are protected from undue hazard or risk, and (3) making recommendations for improving human subject protection. FDA subsequently established a new unit, the Good Clinical Practice Program, within the Office of Science and Health Coordination in the Commissioner's Office, to coordinate and direct human subject protection, good clinical practice issues, and bioresearch-monitoring program policy. In June 2006, FDA announced an initiative to strengthen its oversight and protection of subjects in clinical trials and the integrity of resulting data as part of its Critical Path Initiative. FDA is defining cross-center goals and developing a quality system for its bioresearch-monitoring program.

OIG currently has a study underway to evaluate FDA's implementation of our June 2000 report's recommendations and to revisit FDA's ability to oversee clinical trials. More specifically, this study focuses on FDA's inspections of clinical trials. However, the study does not specifically address whether the Bioresearch Monitoring program is effective in identifying clinical investigators whose practices or conduct may compromise the quality and integrity of clinical data or the safety of individuals participating in them.

Our report is expected to be published soon. Once the report is published, we would be happy to share a copy with your committee.

You also asked whether FDA has implemented guidance regarding the definition of "repeated or deliberate" violations of FDA clinical trial regulations and requested that OIG examine how this guidance has been implemented. At present, we do not believe that FDA has fully addressed OIG's recommendation to develop internal guidance on thresholds that violations must meet to justify disqualifying a clinical investigator and preventing that person from receiving investigational products. In April 2007, FDA informed OIG that it had established a workgroup to examine the process for disqualification of clinical investigators and to develop internal guidelines on the threshold for disqualification. OIG has not received any subsequent information regarding FDA's progress or plans as of this date, but we will follow up on this matter.

In addition, you expressed concern that FDA has delayed initiating disciplinary proceedings against clinical investigators who engaged in misconduct or imposing punishment after such proceedings. You also asked that we examine whether FDA prioritizes the order in which it pursues disqualification proceedings against clinical investigators and whether FDA has failed to disqualify such investigators in some cases.

Given our current body of ongoing work at FDA (FDA's Oversight of Clinical Investigators; FDA Management of Information Technology Projects; Traceability in the Food Supply Chain; and The Food and Drug Administration's Generic Drug Review Process) it is unlikely that OIG will be able to undertake any new evaluations at FDA in the next couple of months. But as the new fiscal year begins shortly, we would like to engage you and your staff to discuss the potential for developing and conducting a future evaluation on this matter.

We appreciate your interest in our work and your commitment to strengthen oversight and management in human subject protection. If you would like to discuss this matter further, please contact me, or your staff may call Claire Barnard, Director of External Affairs, at (202) 205-9523. An identical letter has been sent to the Honorable Ed Whitfield.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Inspector General

cc: The Honorable Ed Whitfield

ATTACHMENT D

2003-2005 CASES WHERE FDA DID NOT IMPOSE MANDATORY DEBARMENT WHEN REQUIRED BY STATUTE OR PERMISSIVE DEBARMENT AUTHORIZED BY STATUTE[1]

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
FDA Enforcement Story, FY 2003			
Dr. Allyn Norman*	**21 U.S.C. §§ 331 and 333, Failure to Establish or Maintain Adequate Records of the Disposition of an Investigational New Drug**	10/28/2002	Allyn Norman falsified data in an investigational New Drug study. OCI's investigation disclosed that **Norman completely fabricated data for six of twelve patients required for this IND.**
Gary Barragato*	**21 U.S.C. §§ 331 and 333, Receiving Misbranded Drugs in Interstate Commerce**	10/24/2002	Naturopathic Physician Gary Barragato claimed he was a doctor and was **illegally treating patients in his Rochester, New York hotel room with unapproved new foreign injectible prescription drugs.** Record checks disclosed that Barragato **had prior state convictions for practicing medicine without a license in TX and NM** and confirmed that he was doing so in Rochester.
Christopher Davis	**1 felony count 21 §§ U.S.C. 331 and 333, Receiving Misbranded Drugs in Interstate Commerce**	7/29/2002	Davis admitted to **breaking in to his former medical practice in order to steal Nubain (Nalbuphine HCI)** from the drug storage drawer in the facility. **Davis admitted to a five year drug addiction with this drug** which is an injectible potent, analgesic intended for moderate to sever pain. Additionally, it was determined that **Davis had tampered with Nubain over a number of years while employed at the clinic and afterwards**, by injecting saline

[1] All cases in this chart are included in FDA's Enforcement Story, a publication issued annually by FDA's Offices of Enforcement and Regulatory Affairs, for Fiscal Years 2003 through 2005. Cases in which an individual is eligible for mandatory debarment have been marked with an asterisk; cases in which an individual is eligible for permissive debarment have been marked with a cross.

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
			solution back into the vials after removing some of the Nubain for personal use.
James Duncan*	**18 U.S.C. § 371, Conspiracy** **21 U.S.C. §§ 331 and 353, Knowingly and Intentionally Conspiring to Sell and Trade Drug Samples** **26 U.S.C. § 7206, Filing a False Tax Return**	7/23/2002	Over the course of several years, Duncan, a Proctor and Gamble representative, diverted and sold pharmaceutical drugs. At the time of his arrest, **Duncan was found to be in possession of 11 registered handguns** that were subsequently seized by the Suffolk County Licensing Bureau. As a condition of his release, **Duncan surrendered several rifles, approximately 250,000 rounds of ammunition and a flak jacket** to the Suffolk County Police Department.

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
FDA Enforcement Story, FY 2004			
John D. Copanos*	Committed a felony previously and was debarred by FDA in 1996 **18 U.S.C. § 371, Conspiracy**	9/9/2003	In 1996, FDA permanently debarred John D. Copanos from managing Consolidated Pharmaceutical Group. In May, 1999, an investigation found that Copanos continued to substantially participate in and direct drug manufacturing operations at CPG.
James H. Coleman*	**18 U.S.C. § 1001, False Statements**	3/27/2001	After Copanos (see above) was convicted and debarred in 1996, Coleman provided affidavits to a court, assuring it that Copanos would not be involved with Consolidated Pharmaceutical Group ("CPG"). After a federal investigation showed Copanos' continued involvement with CPG, Coleman was convicted for making false statements.
Mary Sawaya*	**18 U.S.C. § 1001, False Statements**	1/22/2004	Sawaya was conducting clinical drug studies without a medical license and had falsified at least 2 medical licenses and provided them to study sponsors. FDA reported in its Enforcement Story that Sawaya was disqualified, however, her name is not included on FDA's disqualification list that is posted on its website.
Victor Souiad*†	32 felony counts of **Title 18 U.S.C. § 1347, Health Care Fraud** 27 counts of Title 21 U.S.C. §§ 353(b)(1)(A) and 353(e)(2)(A) **Unlicensed Wholesale of Prescription Drugs**	9/22/2003	In addition to under-dosing and failing to dose cancer patients with injections of Lupron, it was also determined that Souiad fraudulently billed Medicare and other insurance providers for Lupron injections not administered. As a result of his conviction, Souiad **permanently surrendered all medical licenses**.

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
M. Keith Ives*	**Title 18 U.S.C. § 371 - Conspiracy to Defraud the FDA and to Distribute an Unapproved New Drug; Title 15 U.S.C. 78 - Securities Fraud; Title 18 U.S.C. 2 - Aiding and Abetting; and Title 18 U.S.C. § 1343 - Wire Fraud**	3/15/2003	This case pertains to the distribution of an unapproved drug, securities fraud and wire fraud. The claims of effectiveness for "T-Factor," a purported dietary supplement for treatment of immune system diseases, were based on **clinical studies which the company (Ives Health Company) knew to be false.**
Vimlesh Ahmad, MD*†	**18 U.S.C. § 1347, Health Care Fraud**	10/5/2004	Dr. Ahmad was up-coding bills for the office visits of Medicaid patients as well as distributing pharmaceutical drugs without a physical exam, patient history, or an appropriate treatment plan. A man under her care came to her and allegedly told her that he was over-medicated and wished to reduce his medications. **Dr. Ahmad told him to stay on the high dosages and he later died.** An employee falsified chart notes that were submitted to the life insurance company. At the time of her conviction, **Dr. Ahmad agreed to give up her Washington State medical license, her DEA license, and she agreed not to practice medicine in the United States.**
Gregory Caton*	**18 U.S.C. § 1341, Mail Fraud** **21 U.S.C. §§ 331, 355 and 333, Introduction into Interstate Commerce of Unapproved New Drugs**	5/26/2004	From 1999 to 2003, Caton, President of Lumen Food Corporation, and his employees utilized Alpha Omega Labs to take direct orders for unapproved new drugs. On at least two occasions known to FDA, the items shipped by Caton's firm and used by consumers **resulted in bodily injury and harm.** Additionally, in September of 2003, a federal search warrant was executed at Caton's residence and Lumen Food Corp., at which time **a cache of weapons were found consisting of various rifles and shotguns. Caton was arrested on possession of firearms by a convicted felon.**
Joseph Sanpietro* Laurence Simon* Lawrence Marasco* Vincent Sanpietro*	**18 U.S.C. § 371, Conspiracy to Commit Securities Fraud and Wire Fraud**	8/19/2003	Medi-Hut Inc., a medical and drug wholesaler, headquartered in Lakewood, New Jersey and publicly traded on the NASDAQ was suspected to have been involved in **stock manipulation and the distribution of an unapproved drug called Syntest, a generic**

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
	18 U.S.C. § 1001, False Statements to the SEC. **Vincent Sanpietro, convicted under 18 U.S.C. § 1505, Obstruction of Proceedings**		**hormonal replacement therapy.** FDA's CDER confirmed that Syntest had not been approved by FDA.
Dr. Jorge Elias†	**18 U.S.C. § 1347, Health Care Fraud**	5/28/2004	Dr. Elias committed a PDMA violation by selling and **billing Medicaid and private insurance companies for prescription drug samples.** He also committed health care fraud by **billing Medicaid and private insurance companies for prescription drug vaccines that he received free of charge** from the Vaccines for Children's program administered by the State of Connecticut, Department of Public Health.

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
FDA Enforcement Story, FY 2005			
David Hinkson*	April 2004 - Introduction into Interstate Commerce of a Misbranded Drug and Medical Device. May 2004 - convicted on various tax-related counts. **January 2005 - convicted on three counts of solicitation of murder of federal officials**	1/28/2005	IRS reported that Hinkson's business, Water Oz, was selling misbranded and adulterated mineral waters, in addition to ozone generators (OCI was previously aware of this because FDA's field officers were previously prohibited from inspecting Water Oz in 1999). Perhaps more importantly, Hinkson was arrested in April 2003 when evidence was uncovered that he had **attempted to hire associates to murder the IRS case agent, the Assistant U.S. Attorney and the U.S. District Court judge assigned to this case. In addition, Hinkson allegedly solicited the murder of the children of the AUSA and IRS agent.**
Perry M. Beale†	**18 UCS §1341, Mail Fraud**	5/12/2005	Beale was found to have fabricated the results for radioactive xenon gas clearance testing rates at various hospitals, falsified calibration data regarding mammography machines (in violation of the Mammography Quality Standards Act) and fabricated his academic and professional credentials to be qualified and licensed as a radiation physicist. Beale had previously worked for a genuine radiation physicist, and upon that person's death, Beale purchased all of his testing equipment and falsely assumed the role of a radiation physicist for the deceased person's customer base. Additionally, Beale falsified inspection data and verified that sealed sources of radiation were present and accounted for when in fact they had been disposed of years earlier.
Dr. James A. Holland†	**Pleaded guilty to a misdemeanor under federal**	sentenced 11/21/2005	Dr. Holland participated in clinical cancer drug trials at the Stratton Veterans Affairs Medical Center, and supervised a researcher, Paul

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
	law for failing to establish and maintain adequate and accurate case histories on patients participating in drug studies		Kornak. Kornak falsified documentation regarding patients and study subjects and repeatedly enrolled persons as study subjects who did not qualify under a specific study protocol. Kornak, with criminal negligence, **caused the death of one patient by falsely documenting the results of blood chemistry analysis.** The false documentation allowed the patient to meet the criteria for participation in a study where the patient was administered chemotherapeutic drugs in connection with the study and tied two months later.
Matthew Cahill* Jason Sacks*	**11 counts of violating 18 U.S.C. § 371 and 21 U.S.C. §§ 331 (a) and 333 (a)(2), Conspiracy to Introduce Adulterated and Misbranded Drugs into Interstate Commerce, in particular, DNP**	5/21/2003	Cahill and Sacks sold Dinitrophenol (DNP), a highly toxic industrial chemical, over the internet, encouraging its use as a weight loss drug and **resulting in the death of an individual who purchased it from them.**
Adam Stupak (former Serono Regional Director of Sales)† Rudy Liedtke (owner of RJL Systems)† Serono Executives: Mary Stewart (former VP of Sales)*, John Bruens (former VP of Marketing), Melissa Vaughn (former Regional Sales Director), Marc Sirockman (former Regional Sales Director	**Stupak: on December 21, 2004, convicted of three counts of 42 U.S.C § 1320A-7(b)(2)(A) – Offering to pay illegal remunerations; and 18 U.S.C. 2 – aiding and abetting. Liedtke: on April 19, 2005, convicted of 18 U.S.C. § 371 – Conspiracy to commit an offense against the US. Serono: on October 17, 2005, convicted of 18 U.S.C. § 371 – Conspiracy to introduce into interstate commerce, with intent to defraud or mislead, adulterated medical devices;**	Stupak: 12/21/2004 Liedtke: 4/19/2005 Stewart, Bruens, Vaughn, Sirockman: 4/2005	Serono Labs sold Serostim, a human growth hormone, normally indicated for AIDS wasting. Based on complaints that the company was selling Serostim outside of its approved label indication and had falsified clinical research data submitted to FDA, an investigation was initiated in November 2000. The investigation revealed that Serono had developed a scheme to broaden the indication from AIDS wasting through the use of "bioelectrical impedance analysis" (BIA) tests in order to justify the prescription of Serostim. The BIA was approved for use in health individuals only, but Serono changed the algorithms for the machine and never submitted the change for FDA approval. This change resulted in an increase in unnecessary prescriptions. Serono also marketed Serostim for diseases unrelated to AIDS wasting.

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
	and one count of 18 U.S.C. § 371 – conspiracy to offer and pay illegal remuneration.		Under the criminal settlement, Serono agreed to pay $136.9 million in fines. The company also paid $567 million to settle civil liabilities.
Mark Niehold†	**Arizona Revised Statute 13 3406 - Possession, Use, Administration, Acquisition, Sale, Manufacture or Transportation of Prescription Drugs**	12/23/2004	Niehold, an employee of the Federal Aviation Administration**,** was directing the importation of hGH from China (to be labeled on CBP documents as 'ceramic figures'). An analysis of Niehold's government-issued laptop computer revealed that he continued to distribute hGH over the internet by using his government-issued computer even after he was notified that it was illegal.
Dr. Suvarna Shah*†	**18 U.S.C. 1347 - Health Care Fraud and 26 U.S.C. 7201 - Tax Evasion**	5/20/2004	Dr. Shah, a pediatrician, was selling various prescription drug samples to her patients **and then billing Medicaid** and private insurance carriers for the samples. In addition, she was also billing Medicaid for free prescription drug vaccines she received from the Vaccine for Children's Program administered by the State of Connecticut, Dept. of Public Health.
Biochimica OPOS and Luigi Ratti*	**(Aventis, 2001 - 18 U.S.C. § 371 Conspiracy and Distribution of Adulterated Drugs) 21 U.S.C. §§ 331 and 333, Introduction or Delivery into Interstate Commerce an Unapproved Drug**	5/2/2005	FDA learned that OPOS had falsified FDA submissions related to the locations and methods they used to manufacture Cefaclor and other drug products. OPOS had subcontracted out the manufacture of intermediate ingredients to various different companies. In addition, Ratti **orchestrated the creation and maintenance of false records that were used to mislead FDA during its inspections of OPOS.**
Robert Keenan, MD*	**21 U.S.C. § 846 - Conspiracy to Manufacture MDMA (Ecstasy) and Attempting to Manufacture MDMA**	4/25/2005	Keenan operated weight-loss centers in Maryland where he prescribed and dispensed phentermine to his own patients. At the same time, Keenan distributed the medication to their physicians in other states **under the guise of a clinical study** and without an approval IND. He obtained the bulk phentermine from a colleague in Minnesota and manufactured it using an encapsulation machine.

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES
			Keenan refused all of FDA's attempts to inspect his operation, claiming it constituted "physician compounding" and was thus exempt from FDA's jurisdiction.
Jorge Humberto Forcado*† Clark Carlton Mitchell*† Diana Sotto† Sandra Galvez† Luis Manual Fernandez† Maria Loriga† Beatriz Fernandez† Manuel Ivan Perez† Walter Lefurge†	**Forcado: one count, 18 U.S.C. § 371, conspiracy to commit health care fraud; eight counts in violation of 18 U.S.C. § 1347, health care fraud** **Mitchell: one count, 18 U.S.C. § 371, conspiracy to commit health care fraud; four counts in violation of 18 U.S.C. § 1347, health care fraud** **Sotto and Galvez: conspiracy to defraud the United States and to pay health care kickbacks, 18 U.S.C. § 371; conspiracy to commit health care fraud, 18 U.S.C. § 1349; conspiracy to launder money, 18 U.S.C. § 1956** **Fernandez, Loriga, Fernandez, Perez, and Lefurge pleaded guilty either to conspiracy to defraud the United States and to pay health care kickbacks or conspiracy to commit health care fraud.**	4/27/2005 (Forcado and Mitchell) 10/2/2006 (Sotto and Galvez) Fernandez, Loriga, Fernandez, Perez, and Lefurge pleaded guilty in 2006.	Medical professionals, doctors, billing companies, and clinics conspired to fraudulently bill Medicare for intravenous infusion treatments for HIV medications Neupogen and Procrit, and to fraudulently dispense these medications when it was not medically necessary or was not provided to the patient. Forcado and Mitchell, both physicians, falsified patient medical diagnoses and documents in order to conceal from patients that they were not receiving the Neupogen and Procrit treatments that were billed to Medicare. The doctors' clinics received over $5 million in payments from Medicare for the treatments. Sotto owned a medical billing company that submitted the bills to Medicare. She received over $600,000 in fraudulent proceeds. Galvez falsified therapy sheets in the patient files to make it seem as if the patients were receiving the treatments that were billed to Medicare. The patients were not receiving the treatments. Luis Fernandez managed the clinics and paid kickbacks to patients. Loriga and Beatriz Fernandez provided fraudulent forms to patients to assist in the kickback scheme. Perez recruited patients and paid kickbacks. Lefurge served as a purported patient, and lied to FBI agents investigating the conspiracy.

NAME	CONVICTION	DATE OF CONVICTION	CASE NOTES