

Trends in Healthcare Litigation and Government Investigations: OIG's Focus On Individual Liability



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Overview



- Current Climate
- Spinning off CMPL Liability
- Section 1128(b)(7) Exclusions
- Other Exclusion Authorities
- Section 1128(b)(15) Exclusions
- Effect on Global Resolutions

Current Climate



We are concerned that the providers that engage in health care fraud may consider civil penalties and criminal fines a cost of doing business. As long as the profit from fraud outweighs those costs, abusive corporate behavior is likely to continue. . . . One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, **either directly or because of their positions of responsibility in the company** that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk.


Testimony of Lewis Morris, Chief Counsel to the Inspector General, House Committee on Ways and Means, Subcommittee on Oversight (March 2, 2011).

Spinning Off CMPL Liability



- OIG strategy first initiated in Clearwater labs investigations in 2001
- Divide and conquer
 - Individual or smaller targeted by OIG under CMPL
 - Larger entities targeted by DOJ under FCA
- Particularly effective in context of kickback investigations
- Settlements with individual physicians associated with TAP and Astrazeneca FCA settlements (2003 – 2004)
- Michael Bakst
 - Settled 9/ 25/ 2009
 - Former Executive Director of Community Memorial Hospital (CMH) of Ventura, California
 - Paid \$64,000 for allegedly violating CMPL for AKS, Stark.
 - Was also CMH's Compliance Officer at the same time.

Section 1128(b)(7) Exclusions




- Affirmative (not derivative) exclusion authority
- OIG must establish at hearing before ALJ
- Often basis for negotiated exclusion agreements
 - Emmanuel Bernabe; Nursing home executive. Agreed to permanent exclusion in July 2009.
 - Alleged substandard care provided at nursing facilities under his directions

Other Exclusion Authorities



- Conviction-based authorities have been used when individuals are personally convicted as part of global prosecution.
 - Purdue executives excluded under Section 1128(b)(1) (misdemeanor fraud) and (b)(3) (misdemeanor controlled substances)
 - Former CEO of Intermune, Scott Harkonen, M.D., excluded under Section 1128(a)(3) based on wire fraud conviction

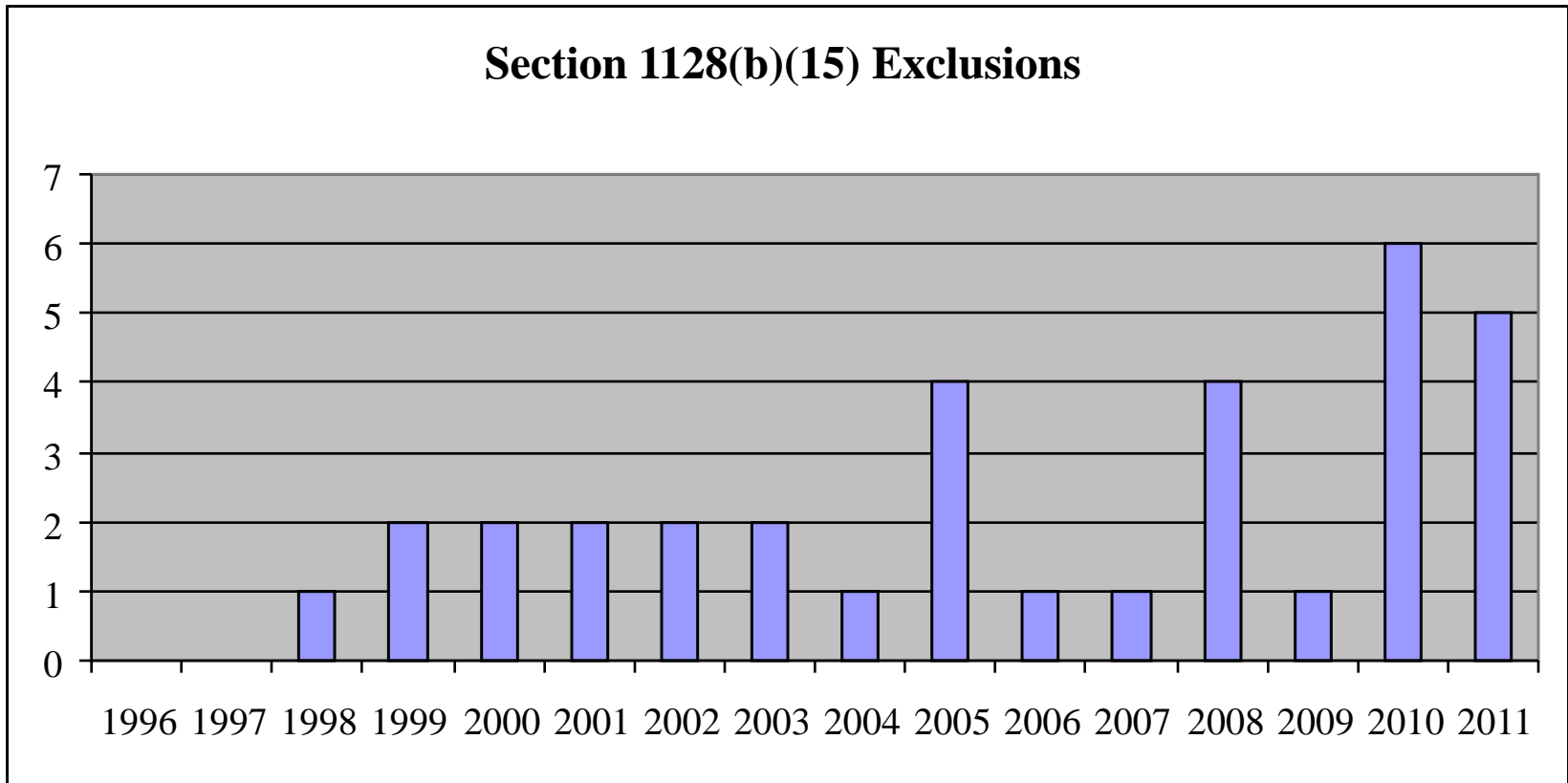
Section 1128(b)(15) Exclusions




- Authority since 1996
- 34 current exclusions reported on LEIE.
- Provider types – Transportation (3), HHA (5), DME (3), Small Group Practices (7), Billing Co. (2), “Drug Company/Supplier” (5), Counseling Center (1), Rehab. Facility (2), Management Services Co. (1), Pharmacy (3), Clinic (2)

OLG's Use of Section 1128(b)(15)

Section 1128(b)(15) Exclusions



Section 1128(b)(15) Guidance



- Issued Oct. 2010
- Factors:
 - Circumstances of the Misconduct and Seriousness of the Offense
 - Individual’s Role in Sanctioned Entity
 - Individual’s Actions in Response to Misconduct
 - Information About Entity
- Sources: Exclusion regulations, DAB exclusion decisions, Nonbinding Criteria (1128(b)(7)), Park Doctrine

Ethex Corporation



- Ethex, subsidiary of KV Pharmaceuticals, plead guilty to felonies for failure to disclose manufacturing problems that led to production of over-sized tablets for two drugs.
- OIG required KV to divest Ethex.
- Marc Hermelin, former CEO of KV, was excluded under Section 1128(b)(15).
- Hermelin subsequently convicted for misbranding.

Forest Labs



- Forest Labs settled FCA case and plead guilty to felony obstruction and two misdemeanors related to off-label promotion
- CEO Howard Solomon proposed for exclusion under Section 1128(b)(15) in April, 2011.
- OIG withdrew proposed exclusion action in August, 2011.

Effect on Global Resolutions



- Resolving cases that include any criminal component has become much more difficult.
- Lack of assurances prior to conviction regarding potential derivative exclusion consequences (particularly permissive).
- Counsel cannot rely on past practices, since evolving focus for OIG.

Questions?



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