Schaeffer Initiative on Health Policy at BROOKINGS

Comments on "Regulating the Innovators: Approval Costs and Innovation in Medical Technologies"

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Summary of Empirical Results

Class III → Class II events ("down-regulation")

- *Patent activity:* Patent flow up 15/year (base 8/year), w/ much from new firms. Mean citations/patent value rise.
- *Product entry:* Flow of new devices up 2.3/year (base 0.5/year), with roughly 30% from new entrants
- *Prices:* Prices of procedures that use devices little changed
- *Adverse events:* Mixed signs, somewhat noisy

Class II → Class I events ("deregulation")

- *Patent activity:* Patent flow up 7/year (base 19/year), albeit noisy, w/ much from new firms. Mean citations/value rise.
- *Prices:* Prices of procedures that use devices fall
- *Adverse events:* Deaths/hospitalizations decline sharply

Agenda

1) A quirk in the FDA adverse event data
2) Interpretation of the results
   - Welfare
   - Generalizability
3) What should device regulators take away?

Adverse Events: Effects vs. Pre-Period Means

Table 4: Effect of Down-Classifications on Adverse Events

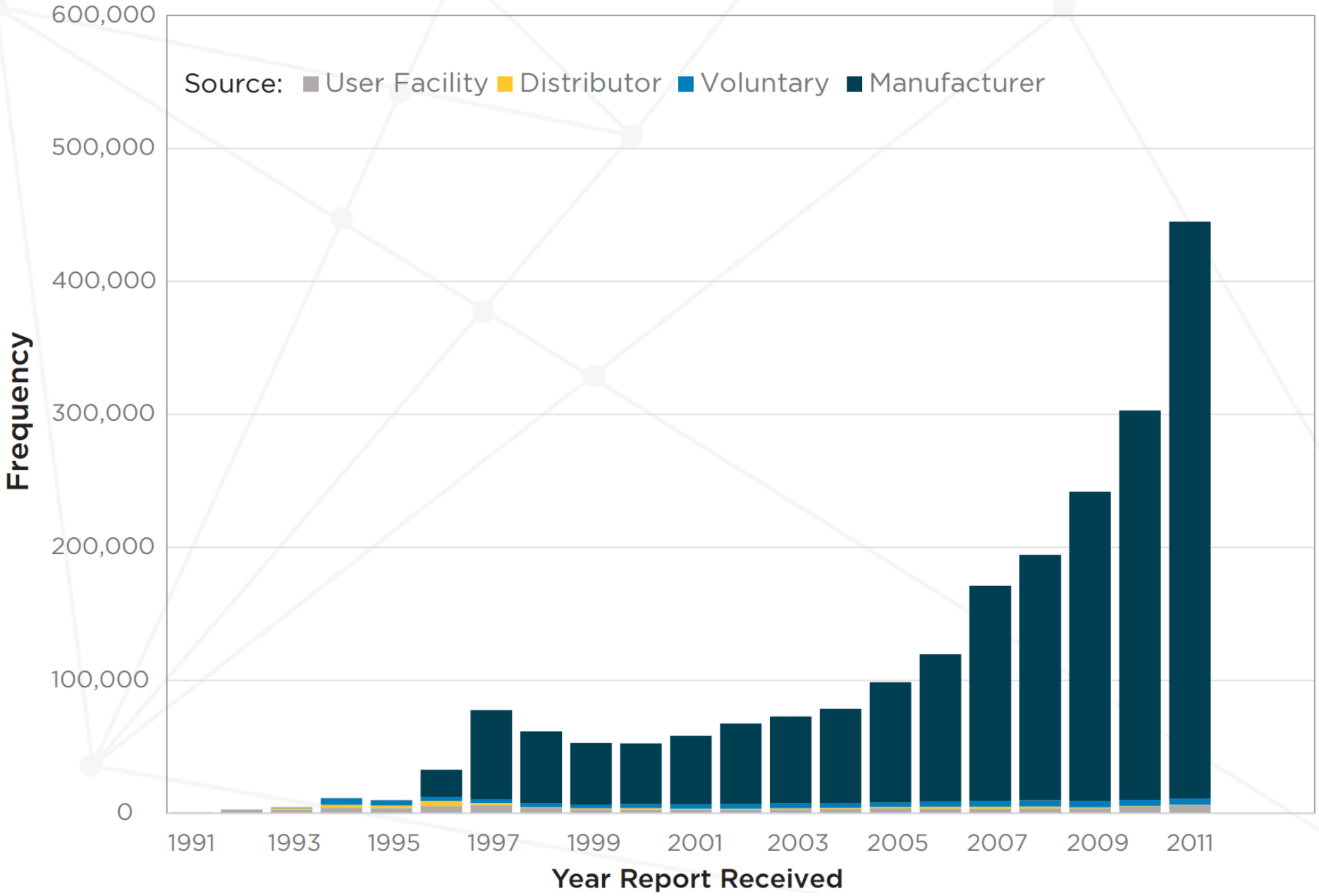
		DID Estimates			
Down-Classification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)	Full (5)
A. Class III to II:					
Emphasis on Safety	0.16	0.073+	-	-	-
	(0.21)	(0.039)	-	-	-
Life-Threatening Event Rate	0.07	0.65	0.89	-0.92	-2.40
	(0.31)	(0.55)	(0.83)	(0.64)	(1.83)
Hospitalization Rate	0.25	2.38+	3.07	1.39	-3.48
	(0.84)	(1.27)	(1.94)	(1.16)	(3.72)
Mortality Rate	0.08	-1.21	1.08	-0.07	0.26
	(0.46)	(2.21)	(0.68)	(0.59)	(2.53)
Sample Size		616	672	552	38472
B. Class II to I:					
Emphasis on Safety	0.065	0.05***	-	-	-
	(0.218)	(0.012)	-	-	-
Life-Threatening Event Rate	0.07	-2.18	-0.36+	-3.24*	-3.18*
	(0.43)	(2.02)	(0.19)	(1.63)	(1.56)
Hospitalization Rate	0.17	-2.05***	-3.04+	-4.87*	-5.44*
	(0.94)	(0.60)	(1.56)	(2.35)	(2.54)
Mortality Rate	0.26	-0.43**	-0.27	-0.46+	-0.57*
	(2.13)	(0.14)	(0.20)	(0.26)	(0.27)
Sample Size		10332	13104	17668	20664

Hypothesis: Changes in MAUDE Coverage

More types of reports reflected in MAUDE over time:

- User facilities (i.e., providers): 1991
- Distributors: 1993
- Voluntary reports: 1993
- Manufacturers: 1996

Figure 1. MAUDE Medical Device Reports through 2013 by Year Received and Reporting Source



Source: Ensign and Cohen (2017)

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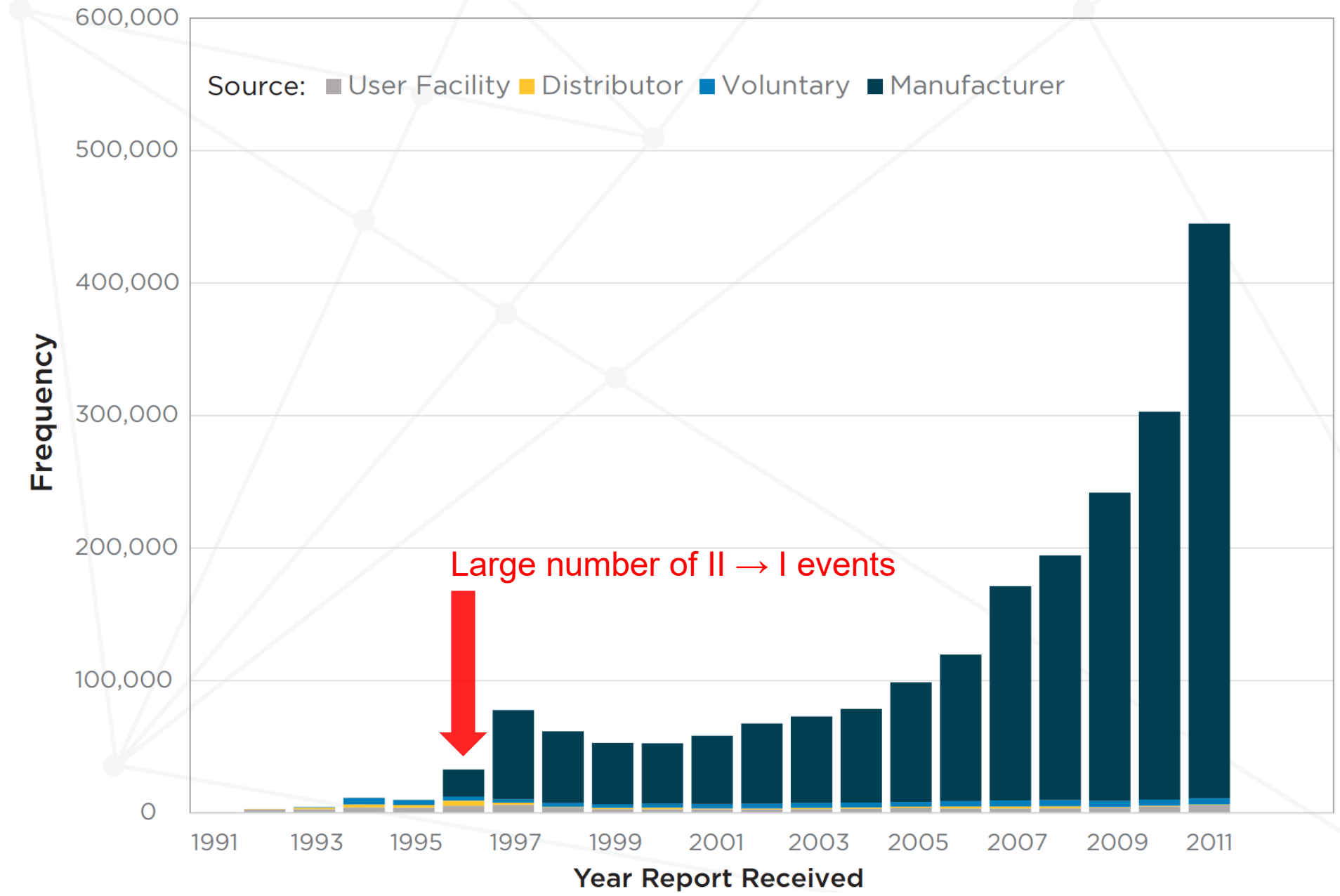

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Implications for Adverse Event Results

Reporting change raises two concerns:

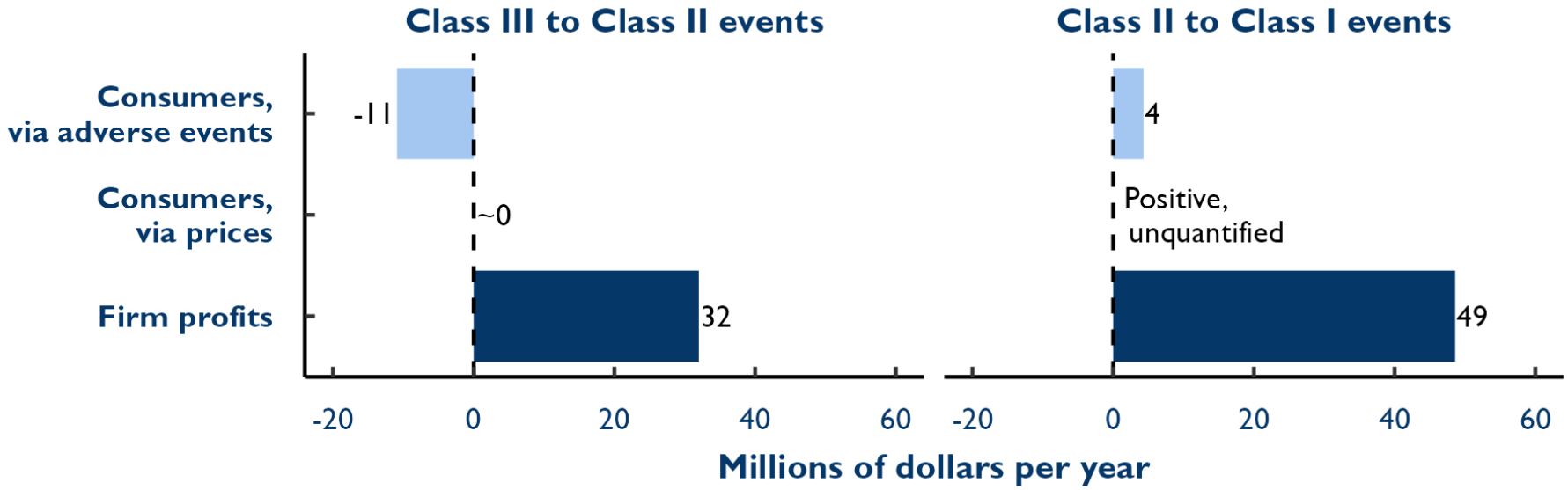
1. Pre-period treatment/control differences may be a poor proxy for counterfactual post-period differences if reporting regimes are very different
2. Pre-period common trends likely less informative than it seems since scale of pre-period outcomes is low

Potential solutions:

- Obtain pre-MAUDE event reports
- Limit to consistently captured report types
- Assess differential effects of change in reporting

How Did These Events Affect Welfare?

Estimated Welfare Effects by Channel and Event Type



Unpacking the firm profits effect:

- Effect = (market value of new patents) x 20%
- Is 20% the right factor? What about R&D costs? What about changes in value of inframarginal patents?

Other effects to consider: Changes in device quality beyond adverse events, scientific value of patents, etc.

How Generalizable Are These Effects?

- *Class III → Class II:* Likely not very. Downgraded devices have very different profiles than other class III devices.
- *Class II → Class I:*
  - Similarity across devices w/ different baseline adverse event rates somewhat reassuring, modulo data quirks
  - *But:* Why were these devices classified differently than "matched" devices to begin with?

What Should Device Regulators Take Away?

Important lesson: Classification decisions (esp. III → II) can have big effects on patent activity/entry

- Broadly consistent w/ US-Europe comparisons for class III devices (Grennan and Town 2020)
- Valuable to have within-US evidence for "marginal" device types (and evidence beyond class III)

But important caveats too:

- Welfare effects murky (for now at least) given quirks in adverse event data, challenges in estimating producer surplus, and various unquantified effects
- For class III → II, effects likely not readily generalizable. Some reason to worry on class II → I also.