

Looking Into the Future Biosimilar Landscape: A Case Study

Federal Trade Commission Public Workshop:
Impact of Recent Legislative and Regulatory Naming Proposals on Competition
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Disclaimer:

The opinions expressed in this presentation are solely those of the presenter and should not be construed to reflect the views of Pfizer.

Biosimilar Naming: Unique Identifier Essential to Safeguard Patient Safety

- Pfizer is committed to the development of innovator biologic products and biosimilars
 - ❖ Pfizer's clinical stage pipeline in biosimilars includes five monoclonal antibodies (mAb) ranging from Phase 1 through Phase 3
- Pfizer has previously called for a balanced, science-based approach to biosimilar naming and labeling*
 - ❖ Each subsequent entry biological product should have a distinguishable identifier (for example, *either* the USAN/INN name followed by the manufacturer's name *and/or* a trade name)
and
 - ❖ Its own label containing a prominent statement regarding its biosimilarity and/or interchangeability status with regard to each indication
- **A distinguishable identifier (either a different non-proprietary name or a trade name) is essential to safeguard patient safety and is supported by regulatory science***

*Pfizer presentation at the Part 11 Hearing before the Commissioner in Nov 2010, as well as written submission to the Docket associated with that Hearing.

Two Case Studies in Traceability of Manufacturer Information in AE Reporting

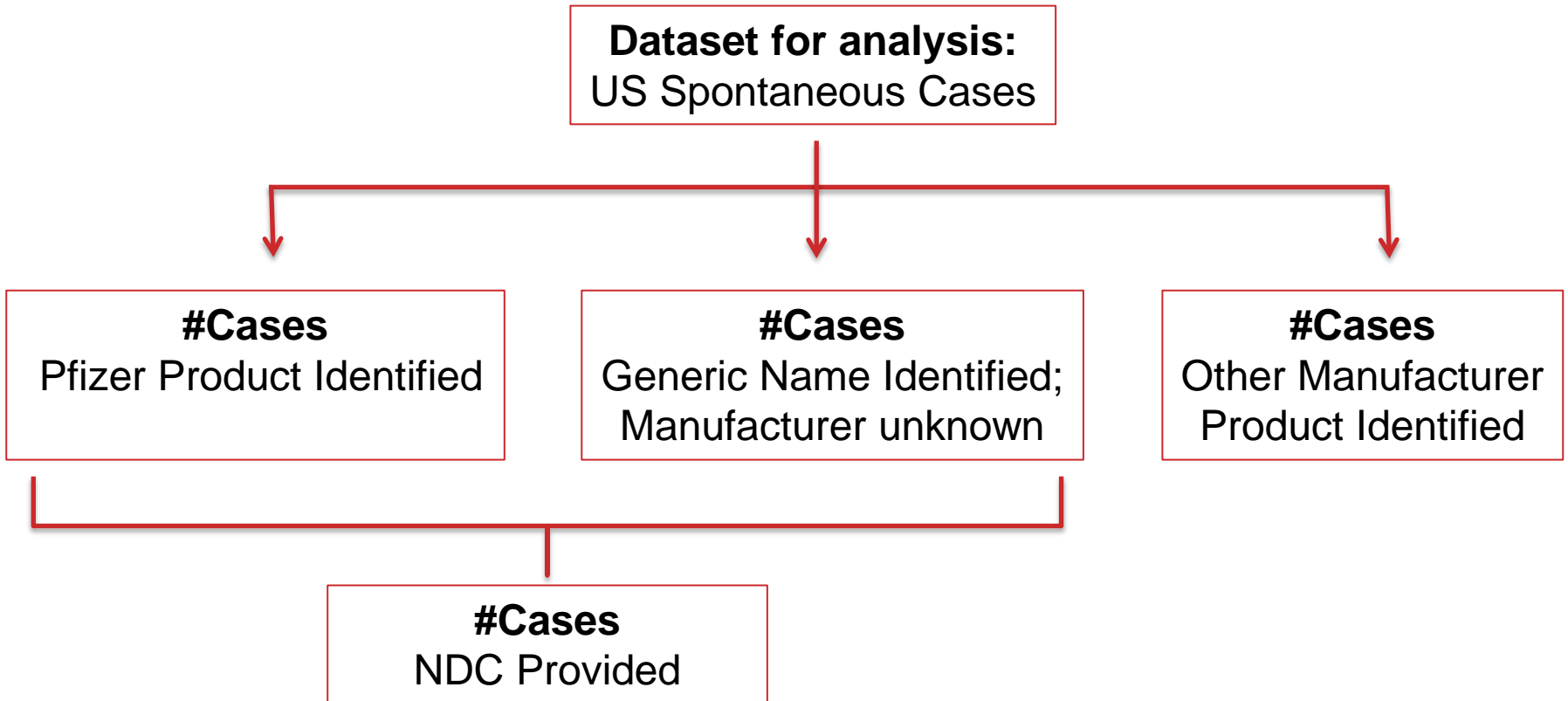
- To inform Pfizer's current position on the "INN Debate", we conducted our own internal research on two case studies that provide insight into the world of AE reporting and the traceability of the manufacturer information in the US

Case Study: Biologic	Case Study: Small Molecule
<ul style="list-style-type: none"><input type="checkbox"/> Multiple branded products<input type="checkbox"/> Same INN<input type="checkbox"/> Not "interchangeable" nor subject to pharmacy substitution<input type="checkbox"/> Physician or self-administered	<ul style="list-style-type: none"><input type="checkbox"/> Branded product + multiple generics on the market<input type="checkbox"/> Same INN<input type="checkbox"/> Interchangeable, and subject to substitution as permitted under state law

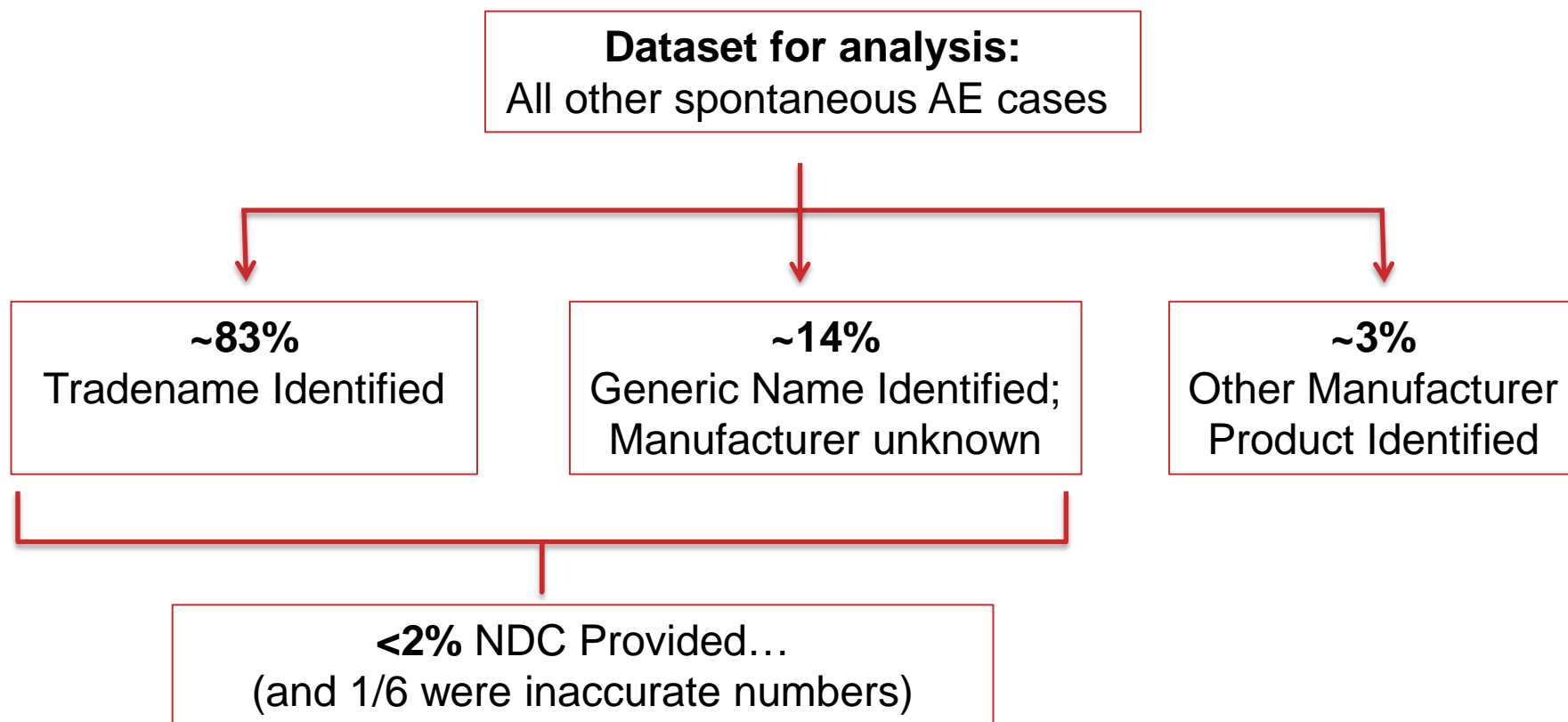
➤ Analysis

- ❖ Primary Objective: To determine the frequency of cases containing identifiable manufacturer information (e.g., trade name provided by reporters) in Pfizer's global safety database
- ❖ Secondary objective: To determine the frequency of cases which specifically included National Drug Code (NDC) information

Methodology:

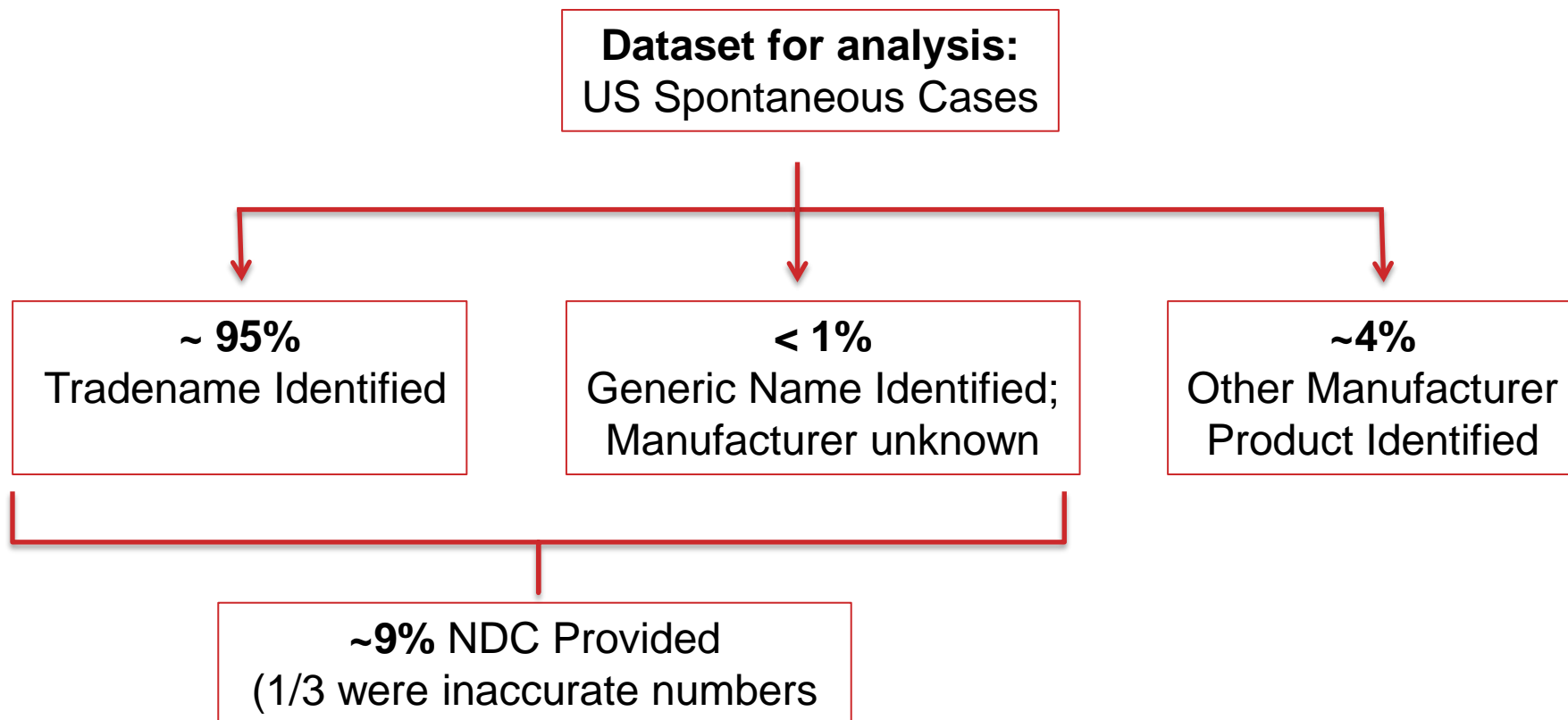


Results: Small Molecule



* Data for 2013

Results: Biologic



*Data for 2009-2013

Case Studies and Lessons Learned

Small Molecule Case Study

- **Results:** *14% of reported AE cases had no identifiable manufacturer*
- **Conclusion:**
 - Use of non-distinct INN, in the absence of distinguishable trade names does not allow AE reports to be accurately linked to the manufacturer
 - **A distinguishable identifier either Trade name or INN is critical**

Biologic Case Study

- **Results:** *Less than 1% of reported AE cases had no identifiable manufacturer*
- **Conclusion:**
 - Distinct trade/brand names allow for more accurate reporting to the appropriate manufacturer irrespective of the INN **in a setting in which all “similar” products have a distinct invented trade name**

In the Absence of a Trade Name, Additional Product-Specific Identifiers are Essential

- Not clear that global agencies can *require* a manufacturer to have a distinct invented trade/brand name
 - ❖ However, given that pharmacovigilance is global, the naming system should also be global.
 - ❖ There are issues of practicality and enforceability of a “mixed” system, in which some products are branded and some have unique INNs.
- In the absence of a specific requirement for a trade name, dual identifiers are critical
 - ❖ The necessity for dual product-specific identifiers is reflected in revised Pharmacovigilance Directive 2010/84/EU which mandates that reporting information include (1) Trade Name and (2) batch number
- Can the NDC function as an additional product-specific identifier in the US?
 - ❖ No. Our primary data show that NDC numbers are rarely reported, and may be inaccurate.
 - ❖ These findings are consistent with other published studies*
- Therefore a distinguishable INN-based identifier, in addition to distinct invented Trade name, would help ensure accurate AE reporting

Summary

- A balanced, science-based approach to biosimilar naming and labeling is needed
- Any naming policy for biosimilar products must be a viable, long-term solution that adequately address safety issues and anticipates the future biosimilar landscape
- A distinct Trade/Brand name is necessary for accurate AE reporting (e.g. Biologic Case Study)
- In the absence of a requirement that all biosimilars and follow-on biologics adopt unique trade names, then it is likely that the identification of manufacturers in AE reporting will be hindered if the products share the same INN (e.g. Small Molecule Case Study)
- **Therefore, both a distinguishable INN plus a specific brand name would increase the accuracy of AE reporting**
 - ❖ For example: INN comprised of common roots plus distinguishable prefixes or suffixes